UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AHOLD USA, INC., on behalf of itself and all others similarly situated, Plaintiff, v. ALLERGAN, PLC (f/k/a ACTAVIS, PLC); ALLERGAN, INC.; ALLERGAN USA, INC.; ALLERGAN SALES, LLC; WARNER CHILCOTT, LIMITED; WARNER CHILCOTT (US), LLC; WARNER CHILCOTT SALES (US), LLC; ZYDUS PHARMACEUTICALS USA INC.; CADILA HEALTHCARE LIMITED, Defendants.	Civil Action No. CLASS ACTION DEMAND FOR JURY TRIAL

CLASS ACTION COMPLAINT

Table of Contents

Plaintiff Ahold USA, Inc., on behalf of itself and all others similarly situated, for its complaint against defendants Warner Chilcott (U.S.), LLC; Warner Chilcott Sales (U.S.) (collectively "Warner Chilcott"); Allergan plc; Allergan, Inc.; Allergan USA, Inc.; Allergan Sales, LLC (collectively "Allergan,"); Zydus Pharmaceuticals USA Inc., and Cadila Healthcare Limited (together "Zydus") allege the following based on (a) personal knowledge, (b) the investigation of their counsel, and (c) information and belief.

I. INTRODUCTION

1. This is a civil antitrust action challenging defendants' unlawful impairment of competition for the prescription drug Asacol. Beginning with Warner Chilcott and continuing after the company became part of Allergan (f/k/a Actavis), the defendants used a variety of anticompetitive practices as part of an overall scheme to block generic competition for the Asacol franchise, harming plaintiff and the class of direct purchasers on whose behalf this action is brought.

2. Asacol (mesalamine 400 mg) was once a blockbuster ulcerative colitis drug. By 2004, the drug generated more than $300 million in annual revenues for its original maker, Proctor & Gamble. By 2012, Warner Chilcott had purchased the rights to Asacol from Proctor & Gamble, and revenue had reached to more than $570 million. Thousands of patients relied on Asacol to manage and prevent their debilitating and life-threatening gastrointestinal symptoms.

3. But by 2012, Warner Chilcott's monopoly was about to disappear. The patent and drug regulation laws guaranteed Warner Chilcott a period of time until patent expiration during which no other manufacturer could create a generic version of the drug. So during this time Warner Chilcott possessed 100% of the market for Asacol, could charge supra-competitive prices, and could reap monopoly profits.

4. But on July 30, 2013, the patents covering Asacol were set to expire. After, that date, for the first time, generic manufacturers could market equivalent, but much less expensive, versions of the drug.

5. Generic companies depend on prescriptions being written for their branded counterparts to drive sales. State laws permit, and often require, that the less expensive generic be substituted for the higher-priced brand at the pharmacy counter. State substitution laws would assure rapid and virtually compete replacement of brand sales with generic sales. Facing the imminent and certain erosion of brand sales due to generic entry and substitution, Warner Chilcott employed unlawful tactics to block generic competition.

6. First, Warner Chilcott developed two new, tweaked formulations of Asacol, Asacol HD and Delzicol, to replace Asacol. The purpose and effect of Warner Chilcott's switch strategy, known in the pharmaceutical industry as a product hop, was to make generic Asacol non-substitutable for the replacement formulations. Neither Asacol HD nor Delzicol were a therapeutic improvement on Asacol. To make Delzicol, Warner Chilcott changed the dosage form from a tablet to a capsule simply by putting a capsule around the Asacol tablet. To make Asacol HD, Warner Chilcott changed the dosage strength from 400mg to 800mg.

7. By moving a substantial portion of Asacol prescriptions to Asacol HD and Delzicol prior to generic versions of Asacol coming to market, the product hop had the intended effect of dissuading generic manufacturers from investing resources to obtain FDA approval for and launching a competing version of Asacol. Through the product hop, Warner Chilcott was able to maintain its monopoly beyond the July 2013 expiration of the patents covering Asacol, and block generic competition.

8. Next, Warner Chilcott used its sales force to switch patients to the new formulations. To accomplish the switch, among other things, Warner Chilcott unlawfully marketed Asacol HD for off-label uses and paid unlawful kickbacks to doctors.

9. Asacol was FDA approved to treat three conditions: mildly active ulcerative colitis; moderately active ulcerative colitis; and the maintenance of remission of ulcerative colitis. Asacol HD, however, was approved only to treat moderately active ulcerative colitis, which accounted for fewer than 10% of Asacol prescriptions. Nonetheless, Warner Chilcott unlawfully promoted Asacol HD to treat the other conditions.

10. Warner Chilcott also paid doctors to switch patients from Asacol to Asacol HD. In April 2016, Warner Chilcott pled guilty to felony healthcare fraud for unlawfully paying kickbacks to prescribers of Asacol and Asacol HD between October 2009 and September 2013.

11. Next, to complete the market switch, on April 1, 2013, Warner Chilcott stopped selling Asacol, leaving the patients who depended on the drug with no choice but to switch to Asacol HD or Delzicol. This maneuver, known in the pharmaceutical industry as a "hard switch," frustrates generic competition by eliminating the prescription base for the reference listed drug before generic competitors can establish a market share, coercing consumers to turn to a drug for which no generic competitor was in the offing, and impeding competition.

12. Warner Chilcott's hard switch was is contrary to the policies underlying federal and state laws designed to promote the accessibility of affordable generic drugs and, independently and as part of its overall scheme, unlawful.

13. Warner Chilcott employed additional anticompetitive tactics. When Warner Chilcott developed Delzicol by placing an Asacol tablet inside a capsule, it acquired the rights to a patent for the capsule and listed the capsule patent in the FDA's Orange Book as covering

Delzicol. Under Hatch-Waxman, this allowed Warner Chilcott to file an infringement suit against any generic competitor seeking approval of a generic Delzicol formulation, and to automatically stay FDA approval of a generic Delzicol application for up to 30 months. But the Orange Book listing was improper because the patent claims only the capsule, not the drug product itself. Warner Chilcott's reliance on the improper Orange Book listing as a basis to elicit a Paragraph IV letter and commence an action triggering a 30-month automatic stay rendered its patent litigation a sham.

14. In addition, after manipulating the market to coerce Asacol purchasers to purchase Asacol HD, Warner Chilcott and Allergan went further, paying a would-be Asacol HD competitor, Zydus, tens of millions of dollars to minimize and delay competition. Even though Zydus announced its intention to challenge the weak patents protecting Asacol HD from competition, Warner Chilcott and Allergan's large and unexplained reverse payment induced Zydus to delay competition until late in 2015, ensuring that the brand products would continue generate many hundreds of millions of dollars more in monopoly profits. As part of the agreement, Warner Chilcott and Allergan promised not to launch an authorized generic of Asacol HD to compete with Zydus, and to deter other generics from competing with Zydus.

15. Warner Chilcott knew that its tactics would impede generic competition and preserve its monopoly. As Warner Chilcott's CEO explained in 2013:

> Generally, the generic company doesn't even get launched because the reference product will be Delzicol . . . There won't be an Asacol out there. We've seen this happen . . . when the generic company got the product approved and by that time the product had moved on . . . As the reference product has changed and then moved on . . . there really isn't much to be substituted.

16. Warner Chilcott and its purchaser Allergan benefitted immensely from this scheme, reaping more hundreds of millions more in revenue from Asacol HD and Delzicol in

2014 than they would have made had generic forms of Asacol been available. Thus, despite patent expiration, the companies continue to retain Asacol monopoly profits under the Delzicol and Asacol HD brands.

17. This suit, brought under federal antitrust laws, seeks to recover the overpayments sustained by direct purchasers of Asacol, Asacol HD, and Delzicol as a result of defendants' unlawful and anticompetitive practices.

II. PARTIES

18. Plaintiff Ahold USA, Inc. is a Maryland Corporation with its principal places of business in Quincy, Massachusetts and Carlisle, Pennsylvania. Ahold brings this action as an assignee of McKesson Corp. During the class period, McKesson purchased branded Asacol HD and Delzicol directly from Warner Chilcott, and Ahold purchased branded Asacol HD and Delzicol from McKesson (and will purchase the generic versions of all Asacol franchise drugs, if and when they become available), at supra-competitive prices, and has thereby been injured.

19. Defendant Allergan plc ("Allergan") is a public limited company incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland. Allergan maintains a place of business in the United States at Morris Corporate Center III, 400 Interplace Parkway, Parsippany, New Jersey, 07054. Until June 15, 2015, Allergan was known as Actavis plc ("Actavis"). Allergan markets branded and generic pharmaceuticals throughout the United States and has commercial operations in the United States and around the world. The company became a successor in interest to Warner Chilcott and Proctor & Gamble when it acquired Warner Chilcott on October 1, 2013.

20. Defendant Allergan, Inc. is a wholly-owned subsidiary of Allergan plc incorporated under the laws of Delaware with its principal place of business at 2525 Dupont Drive, Irvine, California 96212.

21. Defendant Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc incorporated under the laws of Delaware with its principal place of business at 2525 Dupont Drive, Irvine, California 96212.

22. Defendant Allergan Sales, LLC is a wholly-owned subsidiary of Allergan plc incorporated under the laws of Delaware with its principal place of business at 2525 Dupont Drive, Irvine, California 96212.

23. Allergan plc, Allergan, Inc., Allergan USA, Inc., and Allergan Sales, LLC shall be referenced collectively in this complaint as "Allergan."

24. Defendant Warner Chilcott Limited is a wholly-owned subsidiary of Allergan plc and is incorporated under the laws of Bermuda, with its principal place of business at Canon's Court 22, Victoria Street, Hamilton HM12, Bermuda. Warner Chilcott purchased Proctor & Gamble Pharmaceuticals Inc.'s ("Proctor & Gamble") brand-name pharmaceutical business on October 30, 2009 and, with its parents, subsidiaries, and affiliates, sold Asacol.

25. Defendant Warner Chilcott (US), LLC is a wholly-owned subsidiary of Allergan plc incorporated under the laws of Delaware with its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866 and, with its parents and affiliates, sold Asacol.

26. Defendant Warner Chilcott Sales (US), LLC is a wholly-owned subsidiary of Allergan plc incorporated under the laws of Delaware with its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866 and, with its parents and affiliates, sold Asacol.

27. Warner Chilcott Limited, Warner Chilcott (US), LLC, and Warner Chilcott Sales (US), LLC shall be referenced collectively in this complaint as "Warner Chilcott."

28. Defendant Zydus Pharmaceuticals USA Inc. ("Zydus") is a privately-held corporation under the laws of New Jersey with its principal place of business at 73 Route 31 N.,

Pennington, New Jersey, 08534. Zydus is a wholly-owned subsidiary of Cadila Healthcare Limited. Zydus markets and distributes generic drugs for sale throughout the United States.

29. Defendant Cadila Health Care Limited ("Cadila") is a corporation organized under the laws of India with its principal place of business at Zydus Tower, Satellite Cross Roades, Ahmedabad 380015, India. Cadila Healthcare Limited works in concert with its subsidiary, Zydus, to develop, manufacture, and market pharmaceutical products throughout the United States. On July 12, 2016, Cadila announced that Zydus would begin selling generic Asacol HD in the United States.

III. JURISDICTION AND VENUE

30. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by plaintiff and members of the class resulting from defendants' conspiracy to restrain trade in the United States market for Asacol, Asacol HD, and Delzicol. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331(a) and (d), 1337(a), and 15 U.S.C. § 15.

31. Venue is appropriate within this district 15 U.S.C. §§ 15(a), 22 (nationwide venue for antitrust matters), and 28 U.S.C. §1391(b), (c), and (d) (general venue provisions). Defendants transact business within this district; transact their affairs and carry out interstate trade and commerce, in substantial part, in this district; and/or they or their agent may be found in this district.

32. Defendants' conduct was within the flow of, was intended to, and did have a substantial effect on, interstate commerce of the United States, including in this district.

33. During the class period, Warner Chilcott and Allergan manufactured, sold, and shipped Asacol, Asacol HD, and/or Delzicol in an uninterrupted flow of interstate commerce.

34. During the class period, each defendant or one or more of its affiliates used the instrumentalities of interstate commerce to join or effectuate the conspiracy. The conspiracy in which defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

35. The Court has personal jurisdiction over each defendant, because each defendant throughout the United States and including in this District has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY FRAMEWORK

A. Characteristics of the pharmaceutical marketplace

36. The marketplace for the sale of prescription pharmaceutical products in the United States contains a unique and significant feature that can be exploited by a brand name manufacturer to extend its monopoly over a particular product. In most industries, the person who selects a product for purchase also pays for that product. Therefore, normally, the price of the product plays a predominant role in the person's choice of products and, consequently, manufacturers have a strong incentive to lower the price of their product to maintain profitability.

37. In the pharmaceutical marketplace, by contrast, there is a disconnect between the product selection and payment. State laws allow pharmacists only to dispense the drug to a patient that is prescribed by the patient's physician. Thus, the patient's physician chooses the product the patient will receive, with the patient (and in many cases the patient's insurer) having

the obligation to pay for the drug. A patient's inability to obtain a drug without a prescription disconnects the product selection from the payment obligation.

38. Pharmaceutical manufacturers, including Warner Chilcott, can exploit this feature of the pharmaceutical marketplace. Brand manufacturers employ armies of sales representatives, known as "detailers," who descend upon physicians' offices to persuade physicians to prescribe their manufacturer's products. The detailers typically do not discuss the cost of the branded products with the physicians.

39. Physicians typically are not aware of the relative costs of branded pharmaceutical products and that, even when physicians are aware of the relative cost, they are insensitive to price differences, because they do not pay for the products themselves. In consequence, in the pharmaceutical marketplace, price plays a comparatively unimportant role in product selection.

40. Where two manufacturers each sell a drug that serves a similar therapeutic function and each manufacturer uses a significant detailer force, the drugs are often sold at very similar, high prices, thus eliminating any consumer benefit from that "competition." This stands in stark contrast to the circumstance in which the competing seller of an AB-rated, bioequivalent drug is a generic company without a detailer force. There, the generic price is significantly lower than the brand price, and purchasers benefit as Congress intended by the Hatch-Waxman Amendments.

41. When the relative importance of the price between two branded pharmaceuticals, or pharmaceuticals that otherwise are not AB-rated to one another, is low, the price elasticity of demand – the extent to which sales go down when price goes up – is by definition also low, which in turn gives brand manufacturers the ability to raise or maintain price substantially above competitive levels without losing sales. The ability to raise prices above competitive levels

without losing sales is referred to by economists and antitrust courts as market power or monopoly power. Thus, the overall effect of the pharmaceutical industry features and marketing practices described above often is to allow brand manufacturers to gain and maintain monopoly pricing power, restrained only competition from AB-rated generics.

42. Congress sought to address the disconnect, and to restore some of the normal competitive pressures to the pharmaceutical marketplace, by incentivizing the rapid development and sale of generics under the Hatch-Waxman Amendments.

43. And the states have addressed the disconnect by adopting Drug Product Selection laws that permit (or sometimes require) pharmacists to dispense AB-rated generic versions of a when the expensive equivalent brand drug is prescribed. These laws reduce the impact of the disconnect between product selection and payments by creating requirements or incentives to substitute the lower-priced generic for the generic at the pharmacy counter.

44. If the defendants had not unlawfully impaired generic competition with respect to the Asacol franchise drugs, purchasers would have saved hundreds of millions of dollars per year on their purchases of those products. The anticompetitive scheme described herein purposely impaired generic competition to the Asacol franchise drugs.

B. The regulatory structure for approval of brand and generic drugs

1. Approval of new drugs and their associated patents

45. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA"), governs the manufacture, sale, and marketing of prescription pharmaceuticals in the United States. Under the FDCA, the manufacturer of a new drug must obtain FDA approval to sell the drug by submitting a New Drug Application ("NDA"). 21 U.S.C. §§ 301 – 392. An NDA must contain scientific data demonstrating that a drug is safe and effective. New drug applicants,

however, are not required to, and usually do not try to, show that their new drug product is superior to another similar, already approved, product.

46. The NDA must also identify any patents claimed to cover the new drug. 21 U.S.C. § 355(a), (b).

47. When the FDA approves a new drug, it approves the drug for specific indications. The intended indications approved by the FDA are listed in the drug's label. Although physicians may prescribe approved drugs to treat any condition pharmaceutical companies, like defendants, are prohibited from promoting drugs for unapproved, or off-label, indications.

48. After FDA approval, the manufacturer may list in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book") any patents that the manufacturer reasonably believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may list in the Orange Book within 30 days of issuance any patents issued after the FDA approves the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

49. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA performs merely a ministerial act of accepting the listing and maintaining the Orange Book.

2. Approval of generic drugs under the Hatch-Waxman Amendments

50. In 1984, Congress amended the FDCA with the enactment of the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly referred to as the Hatch-Waxman Amendments.

51. The Hatch-Waxman Amendments simplified the regulatory process for generic manufacturers. Previously, generic applicants had to follow the same steps as an applicant filing an NDA, including conducting costly and time-consuming clinical trials to establish safety and efficacy. This delayed approval of generic drugs, or deterred companies entirely from manufacturing generic drugs, and deprived drug purchasers of the benefit of generic competition.

52. Instead, under the Hatch-Waxman Amendments, a manufacturer seeking approval to sell a generic version of a brand drug could file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's NDA. The ANDA filer need demonstrate only that its generic drug is as safe and effective as the corresponding brand drug by showing bioequivalence to the brand drug. Bioequivalence means that, within certain set parameters of variability, the generic product delivers the same amount of active ingredient into a patient's blood stream for the same amount of time as does the corresponding brand-name drug, and hence has the same clinical effect.

53. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating. AB-rated drugs must be bioequivalent to the brand drug and of the same formulation as the brand drug. Thus, for example, a tablet formulation cannot be AB-rated to a capsule formulation, even if it is bioequivalent to the capsule.

54. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients; having the same route of administration and dosage form; and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug

would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

55. Congress enacted the Hatch-Waxman Amendments to expedite the entry of less expensive generic competitors to branded drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

56. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total prescription drug revenue was $300 billion.

57. In addition to the Hatch-Waxman Act, state generic-substitution laws in all 50 states strongly encourage the use of generic drugs. These laws allow, and sometimes require, pharmacists to fill prescriptions for brand drugs with less expensive generic equivalents, unless the prescribing doctor directs otherwise. State substitution laws are specifically designed to address the disconnect between the prescriber, without cost information, and the individuals and institutions who pay but do not choose. Nearly every state requires that products be AB-rated to one another to be substitutable for each other.

3. Paragraph IV certifications

58. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. the patent for the brand drug has expired (a "Paragraph II certification");

iii. the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

59. A Paragraph IV certification constitutes a constructive act of infringement, granting a brand name drug manufacturer standing to sue the ANDA applicant. The right to sue comes with it the power to delay generic approval. If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval of the ANDA until the earlier of (a) 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Until one of those conditions occurs, the FDA may grant only "tentative approval" if it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay, but cannot authorize the generic manufacturer to market its product until that period elapses.

60. Brand drug manufacturers can game the system by suing any generic drug manufacturer competitor filing an ANDA with a Paragraph IV certification, even if the competitor's product does not actually infringe the listed patents, in order to delay final FDA approval of an ANDA for up to 30 months. Such suits, brought for purposes other than to enforce a valid patent that is actually infringed by the generic drug, delay generic competition and enlarge the period for brand manufacturers to maintain their monopolies.

C. The effect of generic drugs on competition

61. The only material difference between generic drugs and their corresponding brand versions is price. Because generic versions of a corresponding brand drug product are commodities that cannot be differentiated, the primary basis for generic competition is price.

62. Due to the price differences between brand and generic drugs, and other institutional features of the pharmaceutical industry, the launch of a generic product results in the rapid shift of purchasers from brand to generic. Thus, once a generic hits the market, it quickly erodes the sales of the corresponding brand drug, often capturing 80% or more of the market within the first six months after launch. This results in dramatic savings for drug purchasers.

63. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand name manufacturer can continue to profitably charge supra-competitive prices. The introduction of a generic drug, however, results in a predictable and rapid loss of revenue for the brand drug seller.

D. The effect of generic drugs on price

64. Typically, generics cost 10-25% less expensive than their brand counterparts when there is a single generic competitor; this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors available. This phenomenon is driven by Hatch-Waxman.

1. The first generic ANDA filer receives a period of statutory or de facto exclusivity

65. Generics may be classified as (i) first filer generics, (ii) later generic filers, and (iii) authorized generics.

66. To encourage manufacturers to seek approval of generic versions of branded drugs, the Hatch-Waxman Amendments grant the first Paragraph IV generic manufacturer ANDA filer a 180-day period to market the generic version of the drug. During this time, the FDA may not grant final approval to any other generic manufacturer's ANDA for the same drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). That is, when a first filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the branded product are either invalid or not infringed by the generic's product, the FDA cannot approve a later generic company's ANDA until that first generic has been on the market for 180 days, or until its first-filer exclusivity has been forfeited or relinquished.

67. First filers that wait until all Orange Book-listed patents expire before marketing their product do not get this 180-day period to market their product without competition from other ANDA generics. Congress created this 180-day period to incentivize generic manufacturers to challenge the validity or enforceability of patents, or to invent around such patents by creating non-infringing generics.

68. This 180-day window is referred to as the first filer's six-month or 180-day exclusivity. The label, however, is a bit of a misnomer: while later ANDA filers must wait six months after the first filer's market entry to get final FDA approval, a brand may market its own NDA-approved product as an "authorized" generic at any time.

69. As Congress recognized in enacting Hatch-Waxman, the 180-day exclusivity period, in which a generic may market free of competition from another ANDA filer, is extremely valuable to the first filer. In some circumstances, even if the first filer is not entitled to regulatory exclusivity for the 180-day period, it may enjoy a period of de facto exclusivity that

protects it from competition with other ANDA filers because the FDA has not yet approved any other ANDAs. In those circumstances, that period of de facto exclusivity is just as valuable as the statutory 180-day exclusivity, but it may last for more or less than 180 days.

2. The first AB-rated generic is priced below the brand

70. The value of first-filer generic exclusivity is greatly diminished if the brand does not launch an authorized generic.

71. Experience and economic research show that the first generic manufacturer to launch prices its product only slightly below the prices of its branded counterpart. Because state substitution laws either require or permit the substitution of an AB-rated generic for a brand-name prescription, the first generic manufacturer almost always quickly captures a large market share. At the same time, although there is a reduction in average price paid for a prescription for the molecule, it is typically small.

72. Most of a first filer's profits are often earned during the exclusivity period.

73. When no other generic is on the market, the first filer prices its product below the brand product, but not as low as if it were facing competition from other generics. Since, in these circumstances, the first filer's product may compete only with the brand, and because the branded company rarely drops the brand price to match the first filer, the first filer does not face the kind of price competition it will when additional generic products are available. A first filer earns substantially greater sales and profits without an authorized generic being marketed alongside it, compared with when an authorized generic is marketed.

3. Later generics drive prices down farther

74. When multiple generic competitors enter the market, the competitive process accelerates and prices drop to their lowest levels. Multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.

75. According to the FDA and the FTC, the greatest price reductions for pharmaceutical products are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic launch results in a near term retail price reduction of as little as 10%, but that with two generic entrants, near term retail price reduction may reach 50%.

76. Soon after generic competition begins, the vast majority of the sales formerly won by the brand shift to generic sellers. In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry.

4. Authorized generics, like all generics, drive the price of a drug down

77. A brand manufacturer may sell a generic version of its own branded drug, a so-called "authorized generic" at any time. An authorized generic is the same as the brand drug but in a different package: it is identical to the brand drug, and manufactured under the brand name drug's NDA, but sold as a generic product through either the brand manufacturer's subsidiary (if it has one) or through a third-party distributor. Competition from an authorized generic substantially reduces drug prices and the revenue of the first filer generic: if the first filer generic has regulatory or *de facto* exclusivity, an authorized generic reduces the revenue of the first filer generic by more than half. Conversely, the absence of an authorized generic can more than double the first-filer's revenue.

78. Authorized generics are priced like other generics and compete on price with other generics. Thus, authorized generics compete aggressively against ANDA generics on price, and can allow the brand manufacturer to retain substantial market share typically lost to a generic competitor by the brand. Pharmaceutical developers facing competition from generics, therefore, have large incentives to compete with their own or licensed authorized generics.

79. But ANDA generic manufacturers have substantial incentives to resist. A 2006 study sponsored by the brand drug company trade group, PhRMA, for example, found that the presence of an authorized generic causes generic prices to be 16% lower than when there is no authorized generic. A 2009 FTC study shows authorized generic entry drives prices lower during the 180-day exclusivity period. And a report by the FTC issued at the request of Congress in 2011 found that authorized generics capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average. Despite the impact on purchasers, generic manufactures can benefit greatly by foregoing timely entry in exchange for forbearance by brand manufacturers on authorized generic entry.

E. Brand manufacturers can employ multiple tactics to block generic competition

80. Competition from lower-priced AB-rated generic drugs saves drug purchasers billions of dollars a year. These savings, however, mean lower profits for brand drug companies. Branded manufacturers thus seek to extend their monopolies for as long as possible, sometimes resorting to any means possible – including illegal means.

1. Product hopping

81. The threat of lost revenue to generic competition incentivizes brand name drug companies to create innovative new products or improvements to old products that offer real medical benefits to patients. But it may also drive them to seek to improperly obstruct generic drug competition by making changes to existing products that offer patients no therapeutic advantage. Brand name drug companies, like Warner Chilcott, sometimes make create these purportedly "new and improved" products for the sole purpose of interfering with the normal brand-to-generic evolution contemplated and encouraged by the Hatch-Waxman Amendments.

82. Such tactics are often referred to as "product hopping," "ever-greening," "line extension," or – in Warner Chilcott's own parlance – "lily padding." Product hopping can be an

enormously effective, albeit improper, anticompetitive way to game the regulatory structure that governs the approval and sale of generic drugs because it frustrates the efforts of federal and state laws designed to promote and facilitate price competition in pharmaceutical markets. But by blocking purchaser access to generics, it imposes anticompetitive harm and overcharges on drug purchases. For this reason it is also illegal.

83. The AB-rating of generic drugs is designed to ensure therapeutic equivalence to the brand name version of the drug (referred to in the Orange Book as the "Reference Listed Drug" or "RLD"). But the AB-rating, like other aspects of FDCA activity, is only concerned with safety and efficacy, not competition. The absence of attention under the FDCA to anticompetitive opportunities inadvertently safety and efficacy imperatives means the regulatory regime can be manipulated by unscrupulous brand manufacturers seeking to maintain supra-competitive profits.

84. Because the AB-rating is so strict, even the slightest tweak to a branded drug, such as switching from a tablet to a capsule, will prevent a generic equivalent of the original RLD from obtaining an AB-rating to the "new" product. As such, pharmacists may not substitute a generic version of, say, a tablet, for a prescription for a branded drug available only as capsule. A brand name manufacturer, like Warner Chilcott, can slightly alter the form or dosage of a product to frustrate generic competition.

85. FDA regulations permit brand manufacturers to seek FDA approval to modify the dosage form and strength of their existing products. A brand manufacturer that anticipates the onset of generic competition to its drug can modify the dosage form, strength, or some other characteristic of its product in order to prevent the anticipated generic product from being AB-rated to the new brand product. Thus, before the generic manufacturer receives FDA approval

for its generic version of the original product and enters the market, the brand manufacturer can get approval for the revised product, unleash its sales force, and get doctors to begin prescribing the revised drug instead of the original drug. Thus, before the original generic enters the market, the brand manufacturer will have switched the market to the revised product and ensured that the generic, having obtained approval to market a generic of the original product, will be without prescriptions for the original to which its product would be substituted.

86. The timing of the product hop is critical. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the market before the revised product, the latter will make very few sales because the revised brand will be much more expensive than the generic of the original brand.

87. It is equally well known that, after a product hop, doctors are unlikely to prescribe the original product because, having switched patients to the revised drug, they will not want to create confusion and anxiety in their patients by switching them back to the generic of the original product. And, of course, as a matter of FDA and state drug selection laws, after a hop, pharmacists cannot switch patients through the efficient mechanism of automatic substitution because the hopped brand product is not AB-rated to the original brand product.

88. Thus, if a brand manufacturer can successfully cannibalize the original product's sales before the generics enter the market, the generics may not *ever* come to market. Automatic substitution at the pharmacy counter is a generic product's only commercially viable means of competing. Once the brand's patents are no longer effective, no one – neither the brand manufacturer nor any generic manufacturers – can profitably market the product on a basis other than price.

89. To ensure that it protects 100% of its monopoly market share, a brand name manufacturer, like Warner Chilcott, make take an additional, even more extreme step: it may withdraw the original drug from the market entirely, just before patent expiration. This tactic is known as a hard switch. By removing the original RLD from the market, brand name drug manufacturers leave patients and their physicians with no choice but to switch to the revised, more expensive drug, even if it offers no therapeutic advantage above the original.

90. Hard switch product hopping leaves potential generic manufacturers with the ability to manufacture and market safe, affordable generic drugs from which drug purchasers would benefit, but no prescription base for the reference product. Generic drug companies depend on prescriptions of the brand name drug to efficiently distribute affordable versions of the drug. But when the brand company forces physicians to stop prescribing the drug by removing the brand drug from the market, there are no prescriptions for which the generic drug may be automatically substituted.

91. Consequently, a hard switch removes generic companies' cost-efficient means of competing with brand drugs, and effectively prevents generic versions of the original drug from ever coming to market. This phenomenon is well-known in the pharmaceutical industry. Brand name manufacturers know that generic versions of drugs are unlikely to come to market if the reference drug has been discontinued prior to patent expiration because the prescription base (and therefore the potential for automatic substitution) has been eliminated.

92. Recently, courts have decried the practice of hard-switch product-hopping, finding it likely that plaintiffs can prove the conduct to be anticompetitive, because "when a monopolist combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, its actions are anticompetitive

under the Sherman Act." *New York* ex rel. *Schneidermann v. Actavis plc* ("*Namenda*"), 787 F.3d 638, 654 (2d Cir. 2015). As the Second Circuit explained, by withdrawing its old product from the market, the manufacturer "crosses the line" from seeking to persuade physicians to accept its revised drug, to coercing them to switch to the revised drug or risk grave medical conditions. *Id*. And hard-switch product hops impede competition by preventing generic substitution. *Id.* at 655.

2. False Orange Book listings

93. Hatch-Waxman section 505(b)(l) requires an NDA applicant to identify the patents associated with the drug product whose approval is being sought. Similarly, the relevant regulations provide that the manufacturer shall list in the Orange Book the patents that claim the drug or a method of using the drug that is the subject of the new drug. 21 C.F.R. 314.53(b)(1)

94. As a result of the brand manufacturer's listing a patent in the Orange Book as claiming the drug product, an ANDA applicant must file a Paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV), 21 C.F.R. § 314.94(a)(12)(i)(A)(4). This in turn gives the NDA holder the opportunity to sue for infringement and obtain an automatic stay of up to 30-months on the FDA's ability to give final approval to the generic applicant.

95. Brand manufacturers can thus game the system by listing in the Orange Book patents that do not in fact claim the drug product because in reviewing patents and patent information in the Orange Book the FDA simply publishes the supplied information in the Orange Book. It does not evaluate the information for truthfulness.

3. Reverse payments

96. Brand name manufacturers have found yet another means of exploiting the Hatch-Waxman Amendments to improperly extend their monopolies at the purchasers' expense. When a generic drug company submits an ANDA with a Paragraph IV certification, the branded company may initiate Paragraph IV litigation against the generic manufacturer.

97. A patent may or may not be valid, and may or may not be infringed. A valid patent excludes all except its owner from the use of the protected product or process, permitting the owner to charge a higher-than-competitive price for the patented product. But an invalidated patent carries with it no such right. Similarly, an uninfringed patent confers no right to exclude.

98. However, by suing, the brand company, irrespective of merit, can automatically delay the entry of generic competitor product for up to 30 months, and then settle that litigation through what is commonly called a reverse payment agreement.

99. Although a civil litigation for damages may resolve with the transfer of something of value from the defendant to the plaintiff, in a reverse payment agreement, the plaintiff instead pays the defendant. That is, a brand name manufacturer, having alleged infringement, pays a generic manufacturer to defer entering the market, and to drop its defenses to the drug company's infringement claim. Such payments allow the brand company to extend in time its monopoly position by sharing its monopoly rents with the generic manufacturer in exchange for delay.

100. Although reverse payment agreements purport to settle patent infringement suits, in making a payment to the accused infringer, the patentee uses unlawfully created market exclusivity and the revenues it generates, rather than the merits of its patents, to delay generic entry and avoid a court decision as to whether the patent is invalid or not infringed. The brand manufacturer effectively shares its monopoly profits with the generic manufacturers as a *quid pro quo* for their agreement to delay competition. The brand and generic manufacturers split between themselves the savings that earlier generic entry would have brought to purchasers.

4. Bottle-necking the market

101. In many circumstances, a first filer can help the brand manufacturer game the system by delaying not only its own market entry, but also the market entry of all other generic

manufacturers. By agreeing not to begin marketing its generic drug, the first generic applicant delays the start of any relevant 180-day period of generic market exclusivity, sometimes referred to as exclusivity parking. This tactic creates a bottleneck because later generic applicants cannot launch their generics until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

102. The brand manufacturer and first filer frequently fortify the bottleneck by making it less economically viable for subsequent filers to trigger the first filer's exclusivity. For instance, reverse payment agreements often include provisions allowing the first filer to enter the market before the later date otherwise agreed with the brand manufacturer if a subsequent filer succeeds in entering the market before that later date. The co-conspirators disclose these terms publicly, broadcasting to subsequent filers that even if they incur the substantial expense involved in dislodging the bottleneck, they will be guaranteed to face competition from at least the first filer – and likely others. By eliminating all possibility that subsequent filers will enjoy any period of de facto exclusivity, these provisions significantly reduce the value to subsequent filers of obtaining a court decision that would break the bottleneck.

5. No-AG promises

103. Brand and generic manufacturers often try to disguise reverse payments to avoid liability under the antitrust laws.

104. Drug companies may seek to conceal reverse payment agreements as a promise by a brand manufacturer to refrain from launching an authorized generic version of a drug when its generic competitor brings its product to market. Because the availability of an authorized generic severely diminishes the profitability to a generic manufacturer of launching its own version of a drug, a brand manufacturer's agreement not to launch an authorized generic has tremendous financial value to a first-filer generic manufacturer.

105. Without an authorized generic, the first filer with regulatory or de facto exclusivity is left with 100% of generic sales until a second ANDA generic filer launches. With an authorized generic, the first filer with regulatory or de facto exclusivity obtains just 50% of generic sales. Even a first filer without any exclusivity obtains far more in generic sales without an authorized generic than it does when an authorized generic is launched.

106. Payment to the first filer in the form of an agreement not to launch an authorized generic is the same as a cash payment by the brand manufacturer because the agreement effectively double or more s the revenues and profits of that generic company (if the generic company has regulatory or de facto exclusivity), or increases them somewhat less (if the generic company lacks regulatory or de facto exclusivity), and the brand manufacturer foregoes the substantial sales and revenue that it otherwise would make with its own authorized generic.

107. For a first filer of a branded product that sold hundreds of millions of dollars annually, the difference between selling a generic product without having to compete against an authorized generic and selling in competition with such an authorized generic can amount to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry. No-authorized generic agreements thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

108. But this version of pay for delay is even worse for purchasers than naked cash payments. A no-AG promise – because it hands the generic revenues it otherwise would not make – can buy delay just like a cash payment from the brand to the generic. But without an AG, generic prices are also higher than they would be with authorized generic competition, so

consumers are overcharged twice: first during the period of generic delay, then again while the AG is withheld from the market.

109. For this reason, courts to have considered the effects of No-AG promises have nearly universally found such promises to violate the antitrust laws. As the First Circuit explained in considering a no-AG agreement, a "disguised above-market deal, in which a brand manufacturer effectively overpays a generic manufacturer for services rendered, may qualify as a reverse payment subject to antitrust scrutiny," because they are sufficiently valuable to induce the generic companies to abandon their challenge to weak or invalid patents and refrain from competing in the market. *In re Loestrin 24 Fe Antitrust Litigation*, 814 F.3d 538, 549 (1st Cir. 2016); *see also In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F.Supp.2d 367, 392 (D.Mass.2013) ("This Court does not see fit to read into the opinion a strict limitation of its principles to monetary-based arrangements alone.").

V. FACTS

A. Ulcerative Colitis

110. Ulcerative colitis is a chronic inflammatory bowel disorder that typically causes bloody diarrhea, rectal urgency, tenesmus, and abdominal cramping. It may also affect other body systems, including the skin, eyes, joints, and liver. In the United States, 238 out of every 100,000 people suffer from ulcerative colitis. If untreated or poorly controlled, ulcerative colitis can increase the risk of colorectal cancer.

111. Ulcerative colitis is traditionally a cyclical disorder, meaning that patients are often without symptoms for periods of time, but will then develop another ulcer, or flare.

112. Because there are two cyclical phases to the disease, patients usually need two modes of treatment: one for treatment of active ulcerative flares, and another to prevent flares

from returning. This second type of treatment is known as the "maintenance of remission" therapy.

B. The development of Asacol to treat ulcerative colitis

113. The most common treatment for ulcerative colitis is a class of drugs containing the active ingredient mesalamine, which is in a therapeutic class of drugs containing 5-aminosalicylic acid, or 5-ASA, a derivative of salicylic acid closely related to aspirin.

114. Mesalamine products operate topically, meaning they reduce inflammation upon contact with the inflamed tissue in the colon. The various mesalamine formulations are not interchangeable: they differ primarily by where along the intestinal tract the active ingredient is released. If the mesalamine is released too early – in the stomach or the small intestine – the active ingredient may never reach the colon, and will not provide symptom relief. If the mesalamine is released too late, much of the ingredient will be excreted, and again will not offer relief.

115. In 1984, Dr. Falk Pharma introduced the first effective oral mesalamine therapy, Salofalk. The product succeeded in protecting the mesalamine active ingredient from absorption before reaching the colon because the medication was covered by a pH sensitive, proprietary acrylic coating called Eudragit L. The coating did not dissolve until it was exposed to a pH of 7, in the small intestine, and therefore allowed the mesalamine to remain intact as it traveled through the highly acidic stomach (which has a pH of 1.5 to 3.5).

116. On January 31, 1992, Proctor & Gamble obtained approval for its NDA No. 19-651, earning the ability to market a delayed-release oral tablet containing 400 mg of mesalamine. The drug, sold under the name brand Asacol, was initially approved only to treat mild-to moderately-active ulcerative colitis. Then, on August 19, 1997, the FDA approved Asacol for the maintenance of remission of ulcerative colitis.

117. Asacol was a specific, delayed-release mesalamine formulation that contained a special acrylic-based resin called Eudragit S, which was sold by German pharmaceutical company Evonik Rohm GmbH. Eudragit S dissolves only in alkaline environments (*i.e.*, at a pH *greater* than 7), nearer the colon than Salofalk. This enteric coating allows Asacol tablets to pass through the stomach largely intact, and then release active mesalamine directly into the affected areas of the colon.

118. Proctor & Gamble listed two patents in the FDA's Orange Book as covering Asacol: U.S. Patent No. 5,541,170 ("the '170 patent") and U.S. Patent No. 5,541,171 ("the '171 patent"). Both patents described a manner of using an enteric coating to deliver topical medications to the colon, and noted the invention's applicability to, in particular, 5-amino-salicylic acid (mesalamine).

119. Neither patent covered the active ingredient mesalamine. Both expired on July 30, 2013.

120. Although Proctor & Gamble listed the '170 and '171 patents in the Orange Book, the patents were actually owned by another company, Medeva Pharma Suisse A.G. Medeva provided Proctor & Gamble with an exclusive license over the patents, giving Proctor & Gamble the exclusive, unlimited, and unrestricted right to develop, make, sell, and import the covered delayed-release mesalamine tablets in the United States and other territories.

121. By 2004, Asacol had become one of Proctor & Gamble's best-selling prescription drugs. Asacol was one of the top 100 best-selling pharmaceuticals in the United States that year, with approximately $322 million in U.S. sales.

C. The development of Asacol HD to unlawfully extend Asacol's monopoly profits

122. As with nearly all patent protected drugs, Proctor & Gamble knew that its Asacol profits would end when the applicable patents expired on July 30, 2013. On that date,

competitors would begin to sell affordable generic versions of Asacol, which would quickly capture most sales, as intended by the Hatch-Waxman Amendments and state substitution laws.

123. Proctor & Gamble therefore devised a scheme to retain sales and extend the Asacol monopoly beyond the period provided by the ’170 and ’171 patents.

124. Around October 24, 2004, Proctor & Gamble submitted NDA No. 21-830 for an 800mg, long-acting mesalamine tablet it later marketed as Asacol HD.

125. On May 29, 2008, the FDA approved Asacol HD, but only for the treatment of moderately active ulcerative colitis on May 29, 2008: unlike Asacol, the revised drug was not approved for the treatment of the mildly active ulcerative colitis or maintenance of remission of ulcerative colitis.

126. Proctor & Gamble listed two new patents in the Orange Book for Asacol HD: U.S. Patent No. 6,893,662 and 8,580,302. Both will expire on November 15, 2021.

127. Critical to Proctor & Gamble’s maintenance of the Asacol franchise, Asacol HD was not AB-rated to the original Asacol. Thus, under state substitution laws, pharmacists could not automatically fill a prescription for Asacol HD with a generic version of Asacol.

128. As a result, Proctor & Gamble knew that its product hop would succeed because prescriptions for Asacol HD could not be filled with Asacol, and that it would be able to maintain sales of Asacol HD at brand prices, long after generic versions of Asacol would become available in July 2013.

D. Warner Chilcott purchases the Asacol franchise

129. In the summer of 2009, Proctor & Gamble announced that it would sell its brand pharmaceutical division to Warner Chilcott.

130. Warner Chilcott formally acquired Proctor & Gamble’s interests in Asacol and Asacol HD on October 30, 2009.

131. When Warner Chilcott acquired Asacol, the drug was the 75th top-selling drug in the U.S., with sales of approximately $490 million.

132. At the same time, conventional wisdom cautioned that Asacol had less than four years of immense profitability remaining before generic entry in July 2013 captured most of those profits.

133. But Warner Chilcott had other plans. The main purpose of acquiring Proctor & Gamble's pharmaceutical division was to acquire Asacol because the company thought it could game state substitution laws, the Hatch-Waxman Amendments, and the FDA's overall regulatory structure to prevent a generic version of Asacol from ever having a chance of coming to market.

134. Paul Herendeen, Warner Chilcott's EVP and CFO, explained this "life cycle" management strategy during a 2012 conference call:

> It is worth mentioning here that when we acquired Procter and Gamble's Pharma business, the asset we [coveted] was Asacol, and that was in large part because we believe the uncertain and potentially difficult regulatory pathway for generics could mean that Asacol may enjoy market exclusivity beyond the expiry of the patents around the brand. Based on events that have transpired since we acquired Asacol, we continue to be confident in the prospects for sustaining the Asacol franchise. Of course, one of the other elements of the Asacol franchise that appeals to us, was that the products lend themselves to the development of product improvements that are right in our sweet spot. So I would not expect that we would sit still with Asacol and hope to sustain it over the long haul. You should expect us to actively manage the life cycle of this important franchise. [1]

In other words, Warner Chilcott acquired the Asacol franchise because the company thought it could continue to receive *supra*-competitive profits well into the future by thwarting the federal and state regulations that encourage the use of generic drugs.

[1] Warner Chilcott CEO Discusses 2012 Guidance (Transcript), Jan. 27, 2012 *available at* http://seekingalpha.com/article/322720-warner-chilcott-ceo-discusses-2012-guidance-transcript.

E. Warner Chilcott's hop to Asacol HD and promotion

135. Beginning shortly after its 2009 acquisition of the Asacol franchise, Warner Chilcott exerted extraordinary efforts to switch patients from the original Asacol product to the "new" Asacol HD product. The company knew that if it switched patients to Asacol HD before generic Asacol became available, the patients would stay on Asacol HD after a generic version of Asacol would come to market in July 2013.

136. Warner Chilcott knew this strategy, which depended on patients staying on a particular formulation for long periods of time, would be particularly effective with Asacol. Ulcerative colitis is a lifelong condition and physicians treating ulcerative colitis like to maintain their patients stay on a single drug that works without side effects. As Mr. Herendeen explained:

> When someone is put on Asacol for their ulcerative colitis, it is likely that they [are] put on the product [at] 20 to 30 years old, and they are probably going to be taking that product for the rest of their lives, because it prevents the disease . . . . [I]t is a product that is used in the long term.[2]

137. But there was a hitch in Warner Chilcott's strategy. Asacol HD had received FDA approval *only* for the treatment of *moderately* severe ulcerative colitis flares. The original Asacol had *three* approved indications: (1) treatment of *moderately* severe ulcerative colitis flares; (2) treatment of *mild* ulcerative colitis flares; and (3) maintenance of remission of ulcerative colitis. Asacol was approved for low-dose, long-term maintenance of remission therapy, which accounts for the bulk of Asacol prescriptions. But Asacol HD was approved only for short-term treatment of flares.

138. Indeed, there was no evidence that Asacol HD was safe and effective as a long-term therapy. When initially seeking FDA approval, Proctor & Gamble never sought approval of

[2] Warner Chilcott CEO Discusses 2012 Guidance (Transcript), Jan. 27, 2012) *available at* http://seekingalpha.com/article/322720-warner-chilcott-ceo-discusses-2012-guidance-transcript.

the drug for long-term maintenance of remission therapy. It initially proposed that Asacol HD was superior to Asacol for treatment of mild and moderate flares. But after poor clinical results, Proctor & Gamble was forced to retreat from that position: it abandoned its bid for approval for Asacol HD to treat mild flares, and revised its goal from proving "superiority" in moderate flares to merely proving "non-inferiority."

139. Given the different indications, Warner Chilcott could not legally promote Asacol HD to treat mildly active ulcerative colitis or maintenance of remission therapy, which accounted for the vast majority of Asacol prescriptions.

140. But this did not stop Warner Chilcott. Despite the lack of scientific evidence and legal prohibitions, Warner Chilcott launched an aggressive marketing campaign to switch patients from Asacol to Asacol HD. This became the company's top goal in 2010 and 2011.

141. And in pursuing this goal, Warner Chilcott disregarded the laws prohibiting off-label promotion. As CEO Roger Boissonneault explained when responding to an investor question about the ongoing patient shift:

> [W]e lost a little bit of focus in the fact that convincing clinicians that you shouldn't use the 400 (mg, *i.e.*, Asacol], you should be using the [Asacol] HD. The issue is the reason that you can't use Asacol is not because its 400 milligrams or 800 milligrams. The fact is that it works quickly, it's well tolerated and you can virtually take this for a long period of time.[3]

142. Later in the same conference call, Boissonneault talked about how the Company executed the switch: "we took some [dermatology sales representatives] and we took some

[3] Warner Chilcott PLC's CEO Discusses Q2 2011 Results – Earnings Conference Call (Transcript), Aug. 5, 2011, *available at* http://seekingalpha.com/article/285263-warner-chilcott-plcs-ceo-discusses-q2-2011-results-earnings-conference-call.

[gastrointestinal sales representatives] and put them together it was like a simplistic execution: Just move the 400 milligram to the HD."[4]

143. Warner Chilcott's marketing practices have already faced legal scrutiny. In October 2015, the United States Department of Justice announced that Warner Chilcott pled guilty to felony healthcare fraud for unlawfully paying kickbacks to prescribers of Asacol and Asacol HD (among other drugs) between October 2009 and September 2013. In April 2016, Warner Chilcott was sentenced by U.S. District Court Judge F. Dennis Saylor, IV of the District of Massachusetts to pay a criminal fine of $20.74 million, forfeit $2 million in assets, and pay $197,946 in restitution to two insurance companies. Warner Chilcott also agreed to pay $102.06 million to resolve related civil litigation that Warner Chilcott caused false claims to be submitted to federal health care programs.

144. The plea and settlement resulted from a private *qui tam* action that was filed by former Warner Chilcott employees in March 2011. As alleged in the latest complaint, Warner Chilcott's leadership instituted a widespread off-label marketing campaign to switch all Asacol prescriptions to Asacol HD prescriptions, in violation of federal law.[5]

145. As alleged by former Warner Chilcott employees, Warner Chilcott paid various forms of illegal kickbacks to physicians – including expensive dinners, sham speaking fees, golf outings, wine, and other gifts – to induce them to prescribe its drugs, including Asacol HD. Warner Chilcott deliberately misrepresented the clinical evidence supporting Asacol HD as part of its effort to switch patients to the "new" formulation before the '170 and '171 patents expired. And Warner Chilcott punished sales representatives who refused to market Asacol HD for off-

[4] *Id.*

[5] Pls.' 3d Amended Compl. ¶¶ 384 – 469, *United States v. Warner Chilcott plc*, No. 11-cv-10545 (D. Mass., filed Aug. 8, 2013), ECF No. 45.

label uses by giving them poor performance evaluations. As extensively alleged in the *qui tam* complaint, it was the company's policy to convince physicians to prescribe Asacol HD for all ulcerative colitis patients, not merely those with moderately active ulcerative colitis – the only ulcerative colitis condition for which Asacol HD was approved.

146. As part of the felony plea, Warner Chilcott admitted that its sales representatives paid doctors who prescribed high amounts of Warner Chilcott products with so-called Medical Education Programs. These were really expensive dinners that contained no medical education. They also used Speaker Roundtables, which were pretexts to compensate high prescribing physicians with speaking fees. Warner Chilcott also agreed that it had instructed its sales representatives to submit fraudulent prior authorizations, which allowed physicians to prescribe Warner Chilcott products despite insurers' formulary restrictions.

147. Warner Chilcott also acknowledged that its overall corporate culture was hyper-aggressive and reckless during this period. As admitted in the Criminal Information to which it pled guilty, Warner Chilcott preferred to hire young, assertive sales representatives (described as "Type A, crazy") with no experience in medical sales and even sought such individuals through "a personality test designed to highlight candidates who were aggressive and not sensitive to rules" who could then be counted on to uphold the extremely aggressive "Warner Chilcott way." Warner Chilcott executives referred to those who would not adhere to this culture, many of whom were legacy Procter & Gamble employees, as "creampuffs."

148. In addition to protection from upcoming generic competition, Warner Chilcott received another benefit from aggressively switching patients to Asacol HD. Patients prescribed Asacol HD typically took 15% more milligrams of the drug on a day-to-day basis. This increased the cost of the drug – and Warner Chilcott's profits from the drug – by 15%, even

though Asacol HD has exclusively been approved based on its "noninferiority" to the original product.

149. The Executive Vice President of Warner Chilcott, Paul Herendeen, explained this to investors in a 2010 earnings call:

> One thing you do have to take into account . . . is to the extent that someone has an HD [prescription] versus a 400 [mg prescription], they tend to use more mg per day. It's around 15% more per day. So there is that element, to the extent you look at the franchise, and you look at HD, an HD [prescription] is kind of worth 1.15 of an Asacol 400 [mg prescription].[6]

150. And Warner Chilcott enjoyed these additional profits at the expense of patient health and safety. When patients consumed 15% more milligrams of Asacol HD, they were exposed to 15% more mesalamine for absolutely no medical reasons. Asacol HD, in particular, was associated with kidney and liver failure. When Warner Chilcott switched patients from low-dose Asacol to the "new" high-dose formulation, for no legitimate medical reason, it increased patients' risks of suffering these and other potentially life-threatening health risks.

151. Overall, Warner Chilcott's strategy of aggressive and illegal marketing of Asacol HD prior to the expiration of the '170 and '171 patents was remarkably successful, especially since Asacol HD was not approved for either mildly-active ulcerative colitis or maintenance of remission, which made up the vast majority of Asacol sales. In 2010, Asacol HD accounted for only 9% of Warner Chilcott's total Asacol franchise sales. By 2012, as a direct result of Warner Chilcott's sustained off-label marketing campaign, Asacol HD sales accounted for 28% of the franchise.

[6] Warner Chilcott Limited's CEO Discusses Q3 2012 Results – Earnings Call Transcript, Nov. 9, 2012, *available at* http://seekingalpha.com/article/995041-warner-chilcott-limiteds-ceo-discusses-q3-2012-results-earnings-call-transcript.

F. Warner Chilcott's hop to Delzicol and promotion

152. Even though Warner Chilcott had enjoyed success from its scheme of off-label promotion of Asacol HD, it nevertheless realized it stood to lose the vast majority of its Asacol franchise sales once the '170 and '171 patents expired on July 30, 2013.

153. In 2012, the original Asacol product still accounted for 72% of the Asacol franchise's U.S. sales. The market had sent a clear message to Warner Chilcott: patients and prescribers did not prefer Asacol HD over Asacol. Warner Chilcott had not been successful in its three-year quest (unsupported by scientific evidence) to convince patients and physicians that Asacol HD was an improvement over Asacol. Furthermore, Warner Chilcott's sales data showed that, even if the company switched half of Asacol patients to the "new" Asacol HD formulation before the summer of 2013, it would still lose hundreds of millions of dollars to generic competition.

154. On July 31, 2012, Warner Chilcott submitted NDA No. 204412 to the FDA, seeking approval of another iteration of Asacol – which was *bioequivalent* to Asacol – to be sold under the brand name Delzicol. The FDA approved Delzicol for sale six months later, on February 1, 2013.

155. Warner Chilcott touted Delzicol as a significant improvement to investors and the general public. During an investor call in early January, Boissonneault bragged about the company's ability to innovate: "[t]he approval of Delzicol, our new 400-milligram delayed-release mesalamine product, provides you with tangible evidence of our ability to successfully develop improved versions of our key product."[7]

[7] Warner Chilcott Management Discusses Q4 2012 Results – Earnings Call Transcript, Feb. 22, 2013, *available at* http://seekingalpha.com/article/1216961-warner-chilcott-management-discusses-q4-2012-results-earnings-call-transcript.

156. But there was nothing innovative or new about Delzicol. In its application to the FDA, Warner Chilcott identified only two differences between the original Asacol and the "new" Delzicol: (1) Delzicol contains dibutyl phthalate ("DBP") as an inactive coating ingredient, while Asacol contains dibutyl sebacate ("DBS") instead; and (2) Delzicol consists of a cellulose capsule around an Asacol tablet.

157. Moreover, Warner Chilcott's literature used the clinical outcomes of Asacol to demonstrate the clinical safety and efficacy of Delzicol. On its website providing Delzicol prescribing information to health care providers, it stated that "[i]n a pivotal trial, nearly half of patients had improved or were in remission at 6 weeks." But the data accompanying that statement came from a study of Asacol.[8]

158. And to top it off, the FDA approved Delzicol based on its bioequivalence to Asacol. Warner Chilcott established bioequivalence by submitting a comparative pharmacokinetic study and comparative dissolution studies showing that Delzicol acted similarly to Asacol in the human body. Warner Chilcott did not conduct additional clinical efficacy trials or additional safety trials in support of its Delzicol application.

159. The substitution of DBP for DBS is not an innovation, even for the Asacol franchise, and was not motivated by patient safety concerns.

160. Warner Chilcott attempted to justify the development of Delzicol under the pretext of addressing safety concerns surrounding DBP. Warner Chilcott dishonestly claimed that the FDA's safety concerns regarding DBP prompted it to withdraw Asacol from the market and create Delzicol with a new NDA.

[8] http://www.delzicolhcp.com/efficacy.aspx.

161. But the FDA had made clear as early as 1997 that the preferred administrative process for obtaining approval to change inactive ingredients such as DBP was by post-approval supplement to an existing NDA, *not by submission of a new NDA*. This approval process allows manufacturers to make changes to their approved products without submitting a new NDA. Indeed, no pharmacological or manufacturing concern prevented Warner Chilcott from simply substituting DBS for DBP in Asacol using this process rather than filing a new NDA.

162. Moreover, both Asacol and Asacol HD have always contained DBP. Asacol delivers approximately 21 mg of DBP daily at the maximum recommended dosage of Asacol. Asacol HD contains more than twice as much DBP: 48 mg of DBP at the maximum recommended dosage. Indeed, Warner Chilcott's foreign subsidiary, Warner Chilcott Canada Co., continued to sell Asacol and Asacol HD (in Canada called "Asacol 800") containing DBP to Canadian patients. The company would have introduced DBP-free versions of these products if removing this ingredient resulted in a superior product.

163. Of course, Warner Chilcott would not have undertaken extraordinary efforts, including off-label marketing and illegal kickbacks, to get patients to switch from Asacol to Asacol HD – the latter having over twice the amount of DBP – before the patents expired on Asacol if the company was legitimately concerned about DBP exposure.

164. But a DBP-free version of Asacol would not protect against the destruction of Warner Chilcott's monopoly. Warner Chilcott's sole purpose in including the cellulose capsule was to stop generic substitutability (and to provide an improper regulatory predicate for improper patent litigation, discussed below). Unlike a change in inactive ingredients such as DBS and DBP, switching the product from a tablet to a capsule does prevent an AB-rating and does prevent generic Asacol from being substitutable for the new Delzicol under state pharmacy laws.

165. Warner Chilcott offered no medical justification for switching to a capsule form in its NDA for Delzicol. Indeed, according to the NDA for Delzicol, "no new safety and or efficacy trials were conducted by the Applicant using the proposed capsule product."

166. Similarly, using the empty capsule to cover the Asacol tablet stopped generic substitutability, was entirely unnecessary, did not provide any therapeutic benefits to patients, and was actually harmful to patients due to its size.

167. The new cellulose capsule on Delzicol is covered by U.S. Patent No. 6,649,180 ("the '180 patent"), which expires April 13, 2020. The '180 cellulose tablet patent was originally published by the U.S. Patent and Trademark office nearly a decade before on November 18, 2003. The '180 patent claims a specific "hard capsule formed of cellulose ether film with a specific content of methoxyl and hydroxypropoxyl groups." This patent relates to the new capsule surrounding Delzicol. It is not related to the drug's active ingredient.

168. The addition of the capsule surrounding the Asacol tablet was not medically unnecessary and offers no therapeutic benefit.

169. *First*, Delzicol was approved exclusively on the basis of its bioequivalence to Asacol. Therefore, the Delzicol capsule does not make the overall product medically superior to Asacol.

170. *Second*, the hydroxpropyl methylcellulose ("HPMC") capsule around Delzicol quickly dissolves in stomach acid. By contrast, the enteric coating on the original Asacol – which is concealed within the Delzicol capsule – protects the active ingredient beyond the stomach, all the way to the colon. Thus, the HPMC capsule provides no protection for the enteric-coated Asacol tablet underneath. Enteric coatings, like Eudragit S, are designed to protect active drug ingredients from the acids of the stomach, until they reach the less acidic or

alkaline environment later in the gastrointestinal tract. This renders the HPMC capsule of the Delzicol product a therapeutic nullity, since the enteric coating of the inner Asacol tablet already adequately protects the mesalamine from premature release.

171. *Third*, the capsule modification was not necessary to permit Warner Chilcott to include DBS instead of DBP as an inactive ingredient. Allergan currently sells a DBP-free 400 mg Asacol *tablet* in the United Kingdom. Warner Chilcott did not introduce a capsule product in the United Kingdom, as it did in the United States with Delzicol, because this therapeutically pointless feature would not allow it to game the UK regulatory system.

172. In fact, the capsule is disfavored by patients because, although the tablet inside is identical to original Asacol (but DBP-free), the added capsule makes Delzicol more than 50% larger than the original formulation and patients experienced difficulty swallowing it at a rate twice as high as the original formulation. In April 2014, the FDA issued an Addendum Clinical Review that summarized patients' difficulties swallowing Delzicol compared to Asacol. The FDA referred to 49 instances in which patients had difficulty swallowing Delzicol compared to 18 reported instances in which patients had difficulty swallowing Asacol or Asacol HD.

173. The capsule serves only one purpose: to extend patent protection over Warner Chilcott's Asacol franchise until 2020 and further Warner Chilcott's monopolization scheme.

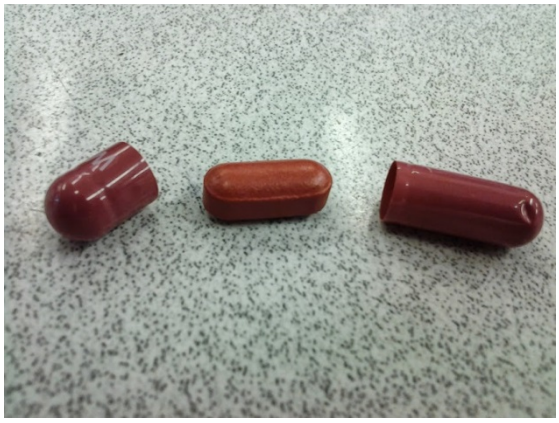
174. But for the '180 patent, generic manufacturers would have been able to sell generic Delzicol as soon as it was introduced and an affordable generic Delzicol equivalent would be on the market today.

G. Patients and physicians did not fall for the hop

175. Shortly after Delzicol's introduction in the spring 2013, purchasers realized that Delzicol was nothing more than an Asacol tablet surrounded by an unnecessary capsule.

176. An Oregon newspaper, *The Bend Bulletin*, recognized the extreme similarity between the two drugs and posted a video on YouTube. The video shows schoolteacher Erin Matlock shaking and then opening a Delzicol capsule, only to find a red tablet that appears identical to "what she was taking before" (meaning Asacol).[9]

177. An ulcerative colitis patient posted a picture on a pharmacy message board on www.reddit.com, an online community forum under the headline "Opened a Delzicol 'capsule' today because it sounded pretty rattly . . . . why?"[10]

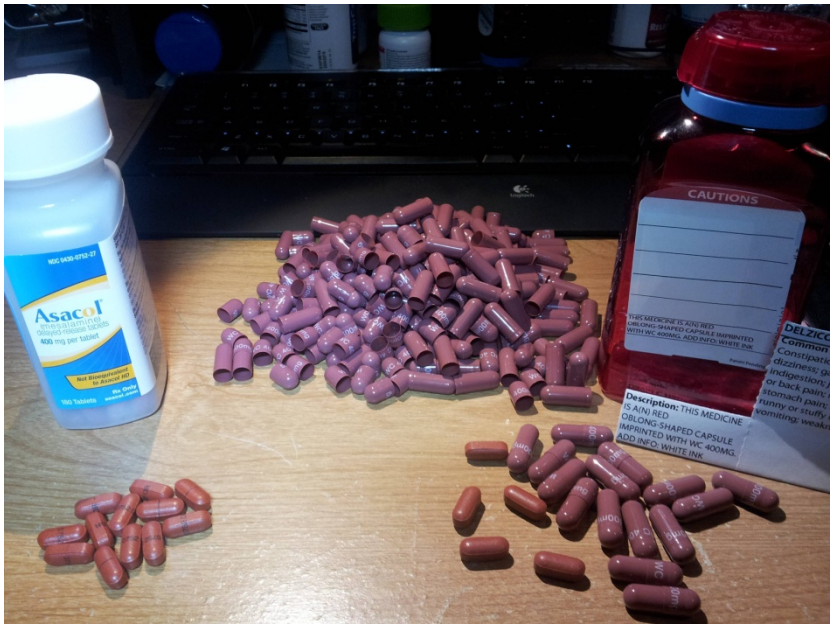


The picture appears to depict a 400 milligram Delzicol with the capsule shell removed. The tablet inside the Delzicol capsule appears to be a solid red Asacol tablet, with the absence of the black-lettering of the pill imprint as the only difference.

178. Another patient created a similar discussion page entitled "The difference between asacol and delzicol," posting a similar photograph:

[9] Bend Bulletin, *Delzicol: How new is it?*, https://www.youtube.com/watch?v=eNtahEEygHI. *See also*, *Delzicol Replacing Asacol*, https://www.youtube.com/watch?v=oIUYFg7wGj8.

[10] http://www.reddit.com/r/pharmacy/comments/1fuhxm/opened_a_delzicol_capsule_today_because_it/.



The Delzicol tablets on the right appear identical to the Asacol tablets on the left, except they do not have the pill imprint "0752 DR," which was the imprint designated for Asacol tablets.[11]

179. A patient on another ulcerative colitis community message board expressed his frustration:

> ==========
> READ THIS AND BE SHOCKED OR HORRIFIED
> ==========
>
> Delzicol = Asacol. Delzicol - the 'new' medication - is nothing more than a 400 mg Asacol tablet in a dissolving capsule. open it up and see.
>
> I used to get 240 tablets for a $20 co-pay - 8 times a day for 30 days. I just paid $170 for 60 tablets to be taken twice a day.
>
> AN ACT OF FRAUD HAD BEEN COMMITTED.
>
> Maybe that's not so shocking or horrifying. I guess the pharma companies just don't make enough money. Private jets and golf cost money.[12]

[11] *See* http://www.drugs.com/imprints/0752-dr-18756.html.

[12] HealingWell.com, May 3, 2013, http://www.healingwell.com/community/default.aspx?f=38&m=2689473&p=6.

180. Warner Chilcott removed DBP from Asacol, put a cumbersome capsule around it, got it approved with a new NDA, and called it Delzicol. The capsule made generic Asacol non-substitutable. And Warner Chilcott left DBP in branded Asacol in order to provide a rationale for removing that product from the market. The product hop therefore provided no benefit other than to Warner Chilcott.

H. Warner Chilcott kills the market for Asacol through a hard switch

181. Even after introducing and aggressively marketing its two slightly altered mesalamine products, most of Warner Chilcott's ulcerative colitis patients remained on Asacol, and would remain so until they switched to affordable generic versions of the drug when the '170 and '171 patents expired in July 2013. Purchasers still clearly preferred the original. As a result, Warner Chilcott expected to lose 80 – 90 % of its Asacol sales to generic competition within a year, as intended by the Hatch-Waxman Amendments and state substitution laws.

182. It is well-known that ulcerative colitis patients generally remain on a successful treatment for long periods of time to avoid the risks associated with switching to a new drug. During a January 2012 conference call, Herendeen acknowledged this feature of the mesalamine prescription market:

> Next let me comment on Asacol. *Asacol is like a battleship. It is hard to change the trajectory of this brand all that much as the market turns over so slowly*. The good news is that this battleship is moving in the right direction, up. Asacol units are relatively steady, and we are able to enjoy growth driving by improved net pricing. So we expect Asacol to fall into the grower category in 2012, and thereafter.[13]

[13] Warner Chilcott CEO Discusses 2012 Guidance (Transcript), January 27, 2012, *available at* http://seekingalpha.com/article/322720-warner-chilcott-ceo-discusses-2012-guidance-transcript (emphasis added).

183. Warner Chilcott knew that, even with Asacol HD and Delzicol on the market, most patients would remain on the original Asacol, eventually switching to generic versions of Asacol when they became available, if given the choice.

184. It is also well-known in the pharmaceutical industry that a brand manufacturer's product hop will be more likely to succeed if it withdraws the original product from the market. Warner Chilcott thus knew that it could cannibalize the entire market, and thereby significantly impair generic competition, by withdrawing Asacol from the market rather than by merely removing DBP from Asacol.

185. Moreover, FDA regulations provide that, in these circumstances, the FDA will refuse to approve any ANDA as to which the delisted product was the RLD if, among other things, the FDA determines that marketing of the RLD was discontinued for safety reasons. By refusing to remove DBP from Asacol and discontinuing the marketing of it, Warner Chilcott intentionally created serious uncertainty as to whether the FDA would approve any ANDAs seeking approval for generic Asacol. Warner Chilcott's purpose was to impair competition from generic Asacol.

186. Warner Chilcott launched Delzicol in March 2013, before the FDA approved any ANDAs for generic Asacol. Then, on April 1, 2013, four months before the patents over Asacol expired, Warner Chilcott removed Asacol from the market. This forced thousands of ulcerative colitis patients, who depended on Asacol to treat their flares or prevent recurrence, to find a different medication. This step, known as a hard switch, finally and completely eliminated the possibility that a generic product could ever be substituted automatically for an Asacol franchise prescription. Warner Chilcott achieved the objective of its illegal product hop scheme.

1. Warner Chilcott's hard switch prevented generic Asacol from launching

187. It is well-known in the pharmaceutical industry that an RLD must be on the market for a generic version of the drug to gain market share. Generic companies rely on automatic substitution for branded drugs at the pharmacy counter to gain sales and successfully compete, as encouraged by state substitution laws and the Hatch-Waxman Amendments.

188. Generic drug companies are able to keep the cost of the products low because they do not need to employ hundreds or thousands of sales representatives to call on doctors and convince them to prescribe their drugs.

189. Warner Chilcott knew that discontinuing Asacol would: (a) eliminate generic manufacturers' only cost-effective means of competing for Asacol sales and (b) secure continuing monopoly profits for itself by denying consumers the ability to purchase generic mesalamine alternatives for the foreseeable future.

190. Warner Chilcott's CEO Boissonneault publicly acknowledged these anticompetitive effects of Asacol's withdrawal. In a 2012 conference call, Boissonneault engaged in the following exchange with Douglas Tsao, a Barclay's Capital employee, and acknowledged the anticompetitive effects of his company's actions:

> **Tsao**: Just a couple of quick ones on Delzicol. First – or actually with Asacol. Do you anticipate managed care will retain Asacol on formularies past 2013 to 2015 and beyond?
>
> **Boissonneault**: That's – well, the issue is it's not going to be available. So to keep it on the formulary, *it's a hard conversion. We're stopping – we're going to stop the shipment of Asacol 400 shortly, and it will be all Delzicol. I think they're all familiar with what's going on.* We're making progress on that front. But the issue is they can keep it on the formulary, but there won't be any Asacol 400 around.
>
> **Tsao**: I guess I was just – the question – the reason for my thinking was just given the potential availability of generics coming in 2014

> and beyond, if they retain it and they could have it as a therapeutic equivalent, sort of what I was curious is on your perspective.
>
> **Boissonneault**: Yes, I've never seen just in my experience that once they go to DELZICOL – I mean, in other words, Delzicol has no substitute. They would have to have a substitute for Delzicol. Even if they kept it on the formulary, physicians – I mean, our first initiative is to get physicians to write Delzicol. But if they had a generic approved, then they'd have to start promoting their own brand.[14]

191. Boissonneault also recognized the anticompetitive effects of removing Asacol later in the same call when responding to a question about generic entry:

> *Generally, the generic company doesn't even get launched because the reference product will be Delzicol. There won't be any Asacol out there*. We've seen that happen with Doryx when the generic company got the product approved and by that time, the product had moved on to, say, to 150 or different, had moved on to a tablet because there really isn't that much business. . . . And basically, as the reference product has changed and then moved on to either tablet or new dose form, there really isn't much to be substituted there.[15]

192. In other words, Warner Chilcott knew that generic versions of Asacol would be abandoned if branded Asacol was withdrawn from the market before the first launch opportunity for generic Asacol in July 2013. And, even if a generic version *wanted to* launch after Warner Chilcott had discontinued sales of Asacol, they would be unable to do so, because the discontinuance caused FDA to delist Asacol as an RLD, meaning FDA could no longer *approve* any generic versions of Asacol. Warner Chilcott's hard switch has effectively destroyed the market for generic Asacol and thwarted generic competition. To date, no generic versions of Asacol are available on the market.

[14] Warner Chilcott Management Discusses Q4 2012 Results – Earnings Call Transcript, Feb. 22, 2013, *available at* http://seekingalpha.com/article/1216961-warner-chilcott-management-discusses-q4-2012-results-earnings-call-transcript (emphasis added).

[15] *Id.*

2. But for the hard switch, at least one generic version of Asacol would have entered the market on July 31, 2013

193. There is substantial evidence that at least one manufacturer would have introduced generic Asacol shortly after the '170 and '171 patents expired. In September 2007, Roxane Laboratories, Inc. gave Proctor & Gamble and patent-holder notice that Roxane had filed an ANDA containing a Paragraph IV certification with respect to Asacol. Roxane had submitted an ANDA to produce generic Asacol that, it claimed, did not infringe on a valid patent covering Proctor & Gamble's Asacol.

194. Roxane's ANDA was supported by a clinical efficacy endpoint study showing that its proposed generic product provided the same relief, in the same time, as branded Asacol.

195. In October 2007, Medeva and Proctor & Gamble filed suit against Roxane for impending patent infringement. The content of this lawsuit shows that Roxane had already made substantial investments in the development of a generic version of Asacol and had reliably produced test batches of generic Asacol.

196. In June 2010, Par Pharmaceutical, Inc. and EMET Pharmaceuticals, LLC notified Warner Chilcott that it had filed an ANDA containing a Paragraph IV certification with respect to Asacol. Again, Warner Chilcott sued its would-be competitor for patent infringement saying it intended to challenge the validity or applicability of Asacol's existing patents.

197. On or about October 14, 2010, Lupin Limited announced that it had reached an agreement with Warner Chilcott plc and its United States subsidiary, Warner Chilcott Company, LLC to settle then outstanding patent litigation regarding two other Warner Chilcott products, Loestrin 24 Fe and Femcon Fe. As part of the settlement, Warner Chilcott agreed that it would allow Lupin to purchase and dispense an authorized generic version of Asacol if a generic version of the drug was introduced by a third party in the United States. This term of the

settlement evidences Warner Chilcott's and Lupin Limited's expectation that a generic version of Asacol would be introduced by a third party in subsequent years.

198. On August 9, 2012, Par Pharmaceuticals and EMET announced that they intended to market a generic version of Asacol upon patent expiration. Par and EMET were not aware that Warner Chilcott intended to eliminate the market for Asacol shortly before they could launch their generic version of the product.

199. In September 2011, Zydus, along with affiliates, indicated that it had submitted a Paragraph III certification with respect to the patents on original Asacol. This meant that Zydus agreed to delay its launch of an FDA-approved version of Asacol until the drug's patents expired in July 2013.

3. The hard switch caused generics to abandon their Asacol ANDAs

200. Each of these manufacturers was developing and seeking regulatory approval for a generic version of Asacol. Absent Warner Chilcott's anticompetitive scheme, at least one of these manufacturers, or others, would have introduced a generic Asacol immediately after patent expiration in summer 2013. These generic manufacturers were well aware of the anticompetitive effects that a product hop away from Asacol would have on their ability to use automatic substitution to compete in a cost-efficient manner, as described above. And since Warner Chilcott had publicly discussed its proposed product hop by February 2013, if not earlier, these generic manufacturers knew by no later than that date that there would be virtually no market left for their generic versions of Asacol by the time the patents expired in July 2013.

201. As a direct result of the product hop, these generic competitors ceased their efforts to obtain FDA approval prior to July 2013. But for Warner Chilcott's anticompetitive product hop, one or more of these generic competitors would not have abandoned their efforts to obtain

FDA approval of their generic versions of Asacol, and would have succeeded in obtaining such approval and entering the market by July 31, 2013.

202. Warner Chilcott knew and intended that its discontinuation of the Asacol would disincentivize all subsequent generics from continuing to seek approval and, ultimately, block their approval altogether. But for Warner Chilcott's discontinuation of Asacol, generic versions of Asacol would have been pursued, approved, and available to consumers beginning July 31, 2013. Warner Chilcott's anticompetitive scheme therefore impeded competition.

203. As of late 2012 there were at least four generic companies (and likely more) actively pursuing approval of generic Asacol in anticipation of a July 2013 launch date. However, when Warner Chilcott announced its product hop plans in February 2013, these generics had reason to believe their hard work might be for naught. And when Warner Chilcott made good on its promise to yank Asacol off the shelves, there could be no doubt in generic's minds that the market they had worked long and hard to introduce generic competition into would evaporate before their first opportunity to launch. As a result, the generic companies had no choice but to abandon their efforts to obtain approval for generic Asacol.

204. History had taught that, frustrating as it was, abandoning their late-stage ANDAs was the only rational thing to do. For instance, in one well-known product hop, the manufacturer of branded TriCor moved the market from one formulation to another, and then another. One generic persevered to approval of the original formulation after the first hop, but it could garner only 1/20th of the market (with the remainder having moved to the second formulation). When the generic manufacturer then filed an ANDA to the second formulation, the brand manufacturer hopped to a third formulation. This time, having learned from experience that continuing to seek

approval was a fool's errand, the generic manufacturer abandoned its ANDA for the second formulation, knowing the market would again evaporate before it could ever launch.

205. The strategy is one all-too-familiar in the industry. It is the same strategy that Warner Chilcott signaled to investors (and generics) with increasing frequency in the lead-up to July 2013 patent expiration. And it is one that generics were acutely wary of, ready to stop work as soon as it became apparent that a product hop would render their ANDAs worthless. And this is the strategy Warner Chilcott ultimately implemented to the dismay of ulcerative colitis patients, payers, and would-be generic competitors.

206. Absent Warner Chilcott's hard switch maneuver, at least one of these ANDA filers and/or others would have continued to seek approval for generic Asacol, and would have launched upon patent expiry in July 2013.

4. The hard switch forced patients to abandon a drug that worked for them

207. Warner Chilcott's removal of Asacol not only blocked access to a lower-cost generic, it also disrupted, without medical justification, the treatment of thousands of ulcerative colitis sufferers. Warner Chilcott's regulatory manipulations likely caused thousands of patients to suffer or fear serious and unnecessary symptoms and complications.

208. Because Warner Chilcott stopped selling Asacol months before generic competition, patients were forced to quickly find other drugs. Once these patients switched, they were unlikely to go back to the original Asacol once a generic version was introduced in the summer of 2013. High transaction costs are associated with switching patients back to a previous medication. For instance, patients who wanted generic Asacol (assuming it ever came to market) would have to obtain a new prescription from their physician, and then change their routine to correspond with the dosing instructions, a transition patients are reluctant to take so long as their current treatment remains effective.

209. Patients expressed frustration and bewilderment at the switch. One patient wrote:

> My doctor's office just called and told me they are discontinuing manufacturing Asacol. There is a new medicine called Delzicol. I was told it's the same medicine as Asacol but it's in a capsule. So I asked about the enteric coating and delivery mechanism but they didn't know. Does anyone have info on this? I am freaking out. :([16]

210. Another patient posted:

> No, No NO! I don't want to start on a new drug. This is ridiculous. I need to get off of this, total BS that they may be compromising people's health and symptoms over halting the manufacture process and pointing to a new drug in its place.[17]

211. And another patient remarked, "I have had 10 years remission with asacol, and like many here, BUMMED OUT about the greedy sub-humans who prey on us."[18]

212. By design, Warner Chilcott's hard switch denied doctors and patients the right to decide whether the benefits of switching to Asacol HD or Delzicol would outweigh the benefits of purchasing a less-expensive generic Asacol. Warner Chilcott could not persuade patients and physicians of the superior merits of the "new" products (recall that Asacol HD was merely "not inferior" to Asacol, and Delzicol was bioequivalent to Asacol). Instead, Warner Chilcott successfully coerced patients into switching from Asacol to Asacol HD and Delzicol products.

213. Warner Chilcott was pleased with its removal of Asacol from the market and its launch of Delzicol in spring 2013. Boissonneault described the ongoing transition in a May 2013 conference call:

> With the groundwork well underway, in mid-March, we began the promotion of Delzicol to physicians. Our gastroenterology and other field sales resources have done a great job of jump starting this important initiative. While it's still early days, I am pleased

[16] *Asacol is being discontinued!*, HealingWell.com (April 1, 2013), http://www.healingwell.com/community/?f=38&m=2689473.

[17] *Id.*

[18] *Id.*

> with the launch strategy of Delzicol and the overall performance of Asacol, Delzicol franchise. The strength of Asacol brand name and excellent managed care coverage have made Asacol HD an additional prescribing option for certain patients during the transition to Delzicol. Again, very early days, but I believe the transition of the franchise is going well.[19]

I. Warner Chilcott's conduct was intended to, and did, harm competition

214. Warner Chilcott's tactics succeeding in excluding would-be generic competitors from their only cost-efficient means of distributing their products – by using state substitution laws.

215. Warner Chilcott's exclusionary motive is illustrated by its willingness to sacrifice short-term profits as part of its anticompetitive scheme. Its decisions to incur the extra costs (and suffer the revenue losses) associated with the change in Asacol dosage form from Asacol tablets to Asacol HD tablets and Delzicol capsules were economically rational only because those changes had the exclusionary effect of impairing generic competition. But for the impact on generic competition, Warner Chilcott would not have invested the resources necessary to reformulate and cannibalize Asacol tablets, because doing so would have been economically irrational.

216. In communications with its shareholders, Warner Chilcott stated that it was losing sales as a result of the unlawful product hop, noting that its Asacol sales decrease "was due primarily to our decision to cease trade shipments of ASACOL 400 mg in the United States as we transitioned from ASACOL 400mg to DELZICOL in March 2013, offset, in part, by an increase in net sales of ASACOL HD (800mg)." Warner Chilcott added: "We expect that the

[19] Warner Chilcott Management Discusses Q1 2013 Results – Earnings Call Transcript, May 10, 2013, *available at* http://seekingalpha.com/article/1423971-warner-chilcott-management-discuss es-q1-2013-results-earnings-call-transcript.

loss of ASACOL 400 mg net sales in the United States will be offset, in part, by net sales of DELZICOL and increased net sales of ASACOL HD (800 mg)."[20]

217. If Warner Chilcott's product hop did not have the effect of impairing generic competition, the product hop would have been a money losing proposition. The product hop made economic sense for Warner Chilcott solely because the hop did have the effect of impairing generic competition.

J. Warner Chilcott Improperly Asserts that the '180 Patent Claims the Delzicol Drug Product

218. In putting the capsule around Asacol, Warner Chilcott not only prevented generic Asacol from being substitutable for Delzicol; it also created the pretext for Warner Chilcott to further abuse the regulatory process by improperly listing a new patent in the Orange Book and then commencing sham patent litigation and obtaining an automatic 30-month stay on competition from generic Delzicol.

219. The cellulose capsule on Delzicol is covered by U.S. Patent No. 6,649,180 ("the '180 patent"), which expires April 13, 2020.

220. Warner Chilcott purports to hold an exclusive license to manufacture Delzicol under the '180 patent. The U.S. Patent and Trademark office originally published the '180 cellulose capsule patent on November 18, 2003. The '180 patent claims a specific "hard capsule formed of cellulose ether film with a specific content of methoxyl and hydroxypropoxyl groups."

221. This patent plainly claims only the empty capsules. It does not claim the Delzicol drug product or any method of using it. Indeed, Warner Chilcott instructs that, "For patients who are unable to swallow the capsules, the capsules can be opened and the inner tablets swallowed."

[20] Press Release, Warner Chilcott Reports Operating Results for the Quarter Ended June 30, 2013 (emphasis added).

222. The drug product for which the Delzicol NDA No. 204412 was approved is a pH-dependent delayed-release product. But encapsulating the enteric-coated tablet in the Delzicol NDA No. 204412 product has no effect on the pH dependency compared to the enteric-coated Asacol mesalamine delayed- release tablets. And the ’180 patent claims do not claim pH-dependent delayed-release capsules. The ’180 patent therefore does not claim the drug for which the Delzicol NDA No. 204412 was approved.

223. Nor does the ’180 patent claim an approved method of using Delzicol. Thus, Warner Chilcott improperly listed the ’180 patent in the Orange Book under 21 U.S.C. § 355(b)(1)(G) and 21 C.F.R. § 314.53(b)(1).

224. As a result of Warner Chilcott’s improper Orange Book listing, Warner Chilcott was able to obtain an automatic stay of up to 30 months on the approval of any ANDA seeking approval for generic Delzicol, further delaying generic entry.

K. Warner Chilcott files sham patent litigation against Teva to obtain the automatic 30-month stay of generic entry

225. On or about July 16, 2015, Teva Pharmaceuticals USA, Inc., a generic drug manufacturer, submitted ANDA No. 207873 to the FDA, seeking to market a generic equivalent of Delzicol. This ANDA contained a paragraph IV certification. On or about that same day, Teva sent to Warner Chilcott a Notice Letter as required by the FDCA.

226. Teva attached a detailed statement of the factual and legal bases for its ANDA certifications for the Orange Book-listed ’180 patent and an offer of confidential access to relevant portions of its ANDA. Teva also made available relevant portions of ANDA No. 207873 to show its formulation would not infringe any valid or enforceable claim of the ’180 patent.

227. The ’180 patent claims a very narrow invention with one independent claim – a specific hard capsule using an HPMC film base with a specific concentration of methoxyl and hydroxypropoxyl groups. The ’180 patent does not, and cannot, claim every HPMC capsule – this is well-known, off the shelf drug delivery technology. Because the capsule offers no therapeutic or pharmacokinetic benefit to the patient, any of many capsules could be used by generic manufacturers without infringing the ’180 patent.

228. On August 31, 2015, Warner Chilcott filed a patent infringement suit against Teva. The suit was filed without regard to the merits solely to obtain the advantage of the 30-month stay based on its having improperly listed the ’180 patent in the Orange Book, as it intended when it listed the ’180 patent in the Orange Book, and was therefore a sham.

229. By suing Teva under the Hatch-Waxman Act, Warner Chilcott delayed FDA approval of generic Delzicol capsules. The FDA receives numerous ANDAs per year and prioritizes those drug applications that are not subject to patent litigation. In the absence of Warner Chilcott’s sham litigation, the FDA would focus more attention on Teva’s ANDA and would approve it before 30 months.

230. Warner Chilcott has thus used the ’180 patent against Teva as an anticompetitive weapon to impair generic competition.

L. Warner Chilcott files sham patent litigation against Mylan to obtain the automatic 30-month stay of generic entry

231. On or about September 28, 2015, Mylan Pharmaceuticals, Inc., a generic drug manufacturer, submitted ANDA 207826 to the FDA, seeking approval to market a generic version of Delzicol in the United States. This ANDA also contained a paragraph IV certification. That same day, Mylan sent the required notice letter to Warner Chilcott.

232. As with Teva, Warner Chilcott filed a sham patent suit against Mylan, claiming infringement of the improperly listed ’180 patent. As with the Teva litigation, Warner Chilcott commenced this lawsuit even though it was objectively baseless, in that no reasonable litigant could ultimately expect success on the merits; and Warner Chilcott was motivated by a desire to impose injury on Mylan, a potential competitor and to obtain the automatic 30-month stay, rather than to obtain legal relief.

233. By suing Mylan under the Hatch-Waxman Act, Warner Chilcott delayed FDA approval of generic Delzicol capsules. The FDA receives numerous ANDAs per year and prioritizes those drug applications that are not subject to patent litigation. In the absence of Warner Chilcott’s sham litigation, the FDA would focus more attention on Mylan’s ANDA and would approve it before 30 months.

234. Warner Chilcott has thus used the ’180 patent against Mylan as an anticompetitive weapon to impair generic competition.

M. Warner Chilcott secures the success of its hard switch by paying Zydus not to compete with a generic form of Asacol HD.

235. Almost as soon as Warner Chilcott had launched its Asacol HD product, it found its anticompetitive scheme at risk from a new threat: imminent competition from an AB-rated version of Asacol HD that Warner Chilcott had worked so hard to promote.

236. On September 26, 2011, Zydus and Cadila filed ANDA No. 203-286 seeking FDA permission to sell a generic version of Asacol HD. Zydus filed a Paragraph IV certification, announcing its intention to challenge the validity or applicability of the patents on Asacol HD. After Zydus notified Warner Chilcott of its intention to challenge the Asacol HD patents, Warner Chilcott sued for infringement. The infringement suit triggered the Hatch-

Waxman Amendment's 30-month stay of any approval for Zydus's product, buying Warner Chilcott time to develop yet another strategy in its battle to protect its Asacol franchise.

237. During the course of the litigation, Actavis acquired Warner Chilcott. Shortly before the parties were set to conduct a bench trial, Warner Chilcott decided to remove the possibility of Zydus entering the market for Asacol HD.

238. After two years of litigation, Warner Chilcott and Zydus announced a settlement agreement in December 2013, which they reduced to writing on June 7, 2014. At the time of the unlawful agreement, the court hearing the patent case had not issued any substantive rulings regarding the merits of the case.

1. The Warner Chilcott/Zydus agreement contained a no-authorized generic promise from Warner Chilcott.

239. While the Warner Chilcott and Zydus described the settlement to the public as a "royalty-bearing license," it was a promise not to launch an authorized generic to compete with Zydus's generic Asacol HD in exchange for a promise to delay introduction of its generic Asacol HD. Under the Exclusion Payment Agreement, Zydus agreed to delay launching its generic Asacol HD until at least November 15, 2015 and possibly as late as July 1, 2016.

240. In exchange, Warner Chilcott paid Zydus in the form of a no authorized generic ("No-AG") agreement. The agreement provided that Zydus would delay entering the market until November 15, 2015 if it entered with a product sold under its own ANDA, and would delay entering the market until July 1, 2016 if it entered with a product sold under Warner Chilcott's NDA. The agreement provided that, if Zydus selected the latter option, Warner Chilcott would not compete against Zydus with an authorized generic version of Asacol HD.

241. As Warner Chilcott and Zydus intended, Zydus chose the option that included later entry and the No-AG promise. Zydus has recently announced that it will begin informing its customers that it will start selling an authorized generic of Asacol HD on August 1, 2016.

242. By restraining competition between Warner Chilcott and Zydus, that option was far more lucrative for Zydus – at the expense of Plaintiff and other purchasers. Specifically, by pledging not to market its own authorized generic product, Warner Chilcott enabled Zydus to make double the unit sales, at a much higher price, all at the expense of plaintiff and other purchasers. The No-AG promise thus served as substantial payment from Warner Chilcott to Zydus in exchange for Zydus's agreement to delay entering the market. Zydus could not have obtained this payment or its equivalent even if Zydus had won the patent litigation against Warner Chilcott.

243. Warner Chilcott made this payment in exchange for Zydus's agreement to delay generic competition to Asacol HD. Absent Zydus's agreement to delay entry into the market with generic Asacol HD, Warner Chilcott would not have agreed to make the payment.

244. Additionally, Warner Chilcott and Zydus both agreed to a provision that would ensure that Zydus would be protected if Warner Chilcott were to manage to shift the market away from Asacol HD to some other version of the product. The protection provision ensured that Zydus, but not purchasers and consumers, would suffer no harm if Warner Chilcott engaged in yet another product hop.

2. The No-AG agreement constitutes a large and unexplained reverse payment

245. A reverse payment is large if it exceeds a brand name company's litigation costs saved by entering into its agreement. Even a conservative estimate of the value of the no-authorized generic agreement disguised vastly outstrips any saved litigation costs.

246. Well established literature concludes that the median costs for an *entire* patent case with more than $25 million at stake is approximately $5.5 million.[21] Warner Chilcott's future expected litigation costs at the time of the settlement with Zydus were much less than that because, among other reasons, the patent case was close to trial at the time of the settlement.

247. The value to Zydus of a No-AG promise can be calculated based on known economics of the pharmaceutical industry.

248. With a no-AG, Zydus would likely take 80% of the brand's unit sales during the six-month no-AG period. Asacol HD's sales during the relevant period are estimated at $488 million. Thus, Zydus would expect capture approximately $390 million worth of brand units annually. With only one generic on the market, Zydus would likely price its product at a 10% discount off the brand's price. This would result in generic sales revenues of approximately $351 million annually.

249. With competition from a Warner Chilcott authorized generic – a second generic – the average generic price would drop from a 10% discount off the brand price to a 50% discount off the brand price. Thus, while generics would still take 80% of brand unit sales, the dollar value of those generic sales here would drop from $351 million to $185 million annually. But Zydus would split those revenues with Warner Chilcott's authorized generic, 50/50, leaving it with $92.5 million.

250. So, with annual brand revenue of $488 million pre-generic entry, with a no-AG Zydus's annual revenues would be $351 million; with AG competition it would be $92.5 million. That yields a difference on annual revenues of $258.5 million.

[21] *See King Drug. Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 417 (E.D. Pa. 2015); *see also* American Intellectual Property Law Association ("AIPLA"), 2011 Report of the Economic Survey – median cost of patent infringement litigation.

251. Since the no-AG last for six months, the value of the no-AG is $129.25. This estimate can be refined after discovery.

252. Warner Chilcott's payment to Zydus exceeded the value that Zydus could have obtained even if it had won the patent infringement litigation.

253. The cost to Warner Chilcott (in lost AG revenue) of the No-AG promise can also be calculated. Warner Chilcott could have made at least $92.5 million.

254. Under the terms of the agreement, Zydus promised not to enter the market until November 15, 2015 at the earliest – 23 months after the settlement was announced. By paying Zydus, the first-filer, Warner Chilcott guaranteed itself at least another 23 months of unencumbered monopoly profits, conservatively estimated to be $935 million.

255. Warner Chilcott and Actavis frequently launched authorized generic versions of their branded counterparts, and have done so with respect to at least the following drugs: Actonel, Actigall, Atelvia, Condylox, Doryx tablets, Emla, Femhrt, Kadian (in at least 7 strengths), Microzide, Norinyl, Nor-Qd, and Tenuate (2 formulations).

256. Defendants have no procompetitive explanation or justification for the payment.

VI. MARKET POWER AND MARKET DEFINITION

257. At all relevant times, the Warner Chilcott/Allergan defendants had monopoly power in the market for Asacol, Asacol HD, and Delzicol (the "Asacol franchise"), because they had the power to raise or maintain the price of Asacol at supra-competitive levels without losing enough sales to made supra-competitive prices unprofitable.

258. A small but significant, non-transitory increase to the price of the Asacol franchise drugs would not have caused a significant loss of sales.

259. The Asacol franchise drugs do not exhibit significant, positive cross-elasticity of demand with respect to price, with any other mesalamine product or treatment for ulcerative colitis, other than the AB-rated generic versions of the drugs.

260. The Asacol franchise drugs are differentiated from all other mesalamine products, and all ulcerative colitis treatments, other than the AB-rated generic versions of the drugs.

261. The Warner Chilcott/Allergan defendants needed to control only the Asacol franchise drugs and their AB-rated generic equivalents, and no other products, in order to maintain the price of the Asacol franchise profitably at supra-competitive prices. Only the market entry of competing, AB-rated generic versions would render the Warner Chilcott/Allergan defendants unable to profitably maintain their prices for Asacol without losing substantial sales.

262. The Warner Chilcott/Allergan defendants also sold the Asacol franchise drugs at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

263. The Warner Chilcott/Allergan defendants have had, and exercised, the power to exclude generic competition to the branded Asacol franchise drugs.

264. The Warner Chilcott/Allergan defendants, at all material times, enjoyed high barriers to entry with respect to the branded and generic Asacol franchise drugs.

265. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show the Warner Chilcott/Allergan defendants ability to control the prices of the Asacol franchise drugs.

266. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show the Warner Chilcott/Allergan defendants ability to control the prices

of the Asacol franchise drugs, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, *inter alia*, (a) the fact that generic versions of each drug would have entered the market at substantial discounts to the brand versions, but for Defendants' anticompetitive conduct; (b) the gross margin was at all times substantial enough to show market power, with the price at least 60% higher than cost of production; and (c) the Warner Chilcott/Allergan defendants never lowered the price the Asacol franchise drugs in response to the pricing of other branded or generic drugs.

267. To the extent proof monopoly power by defining a relevant product market is required, plaintiff alleges that the relevant antitrust market is the Asacol franchise drugs.

268. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

269. The Warner Chilcott/Allergan defendants' market share in the relevant markets was and remains at 100% at all relevant times.

VII. MARKET EFFECTS

270. The Warner Chilcott/Allergan defendants willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. The Warner Chilcott/Allergan defendants designed this scheme to foreclose (with respect to Asacol), delay (with respect to Asacol HD) and discourage (with respect to Delzicol) competition on the merits, for the anticompetitive purpose of forestalling generic competition against its mesalamine-containing product franchise. The Warner Chilcott/Allergan defendants carried out the scheme with the anticompetitive effect of maintaining supra-competitive prices for the relevant product.

271. The Warner Chilcott/Allergan defendants implemented the scheme as described herein. These acts in combination and individually were all undertaken to serve the Warner Chilcott/Allergan defendants' anticompetitive goals.

272. The Warner Chilcott/Allergan defendants' acts and practices as described herein had the purpose and effect of restraining competition unreasonably and injuring competition by protecting its mesalamine-containing products from generic competition. These actions allowed the Warner Chilcott/Allergan defendants to maintain a monopoly and exclude competition in the markets for the Asacol franchise drugs and their AB-rated generic equivalents, to the detriment of plaintiff and all other members of the direct purchaser class.

273. The Warner Chilcott/Allergan/Zydus defendants' exclusionary conduct has delayed generic competition and unlawfully enabled it to sell the Asacol franchise drugs without generic competition. But for the illegal conduct, one or more generic versions of the Asacol franchise drugs would have entered the market t sooner than the agreed upon entry date.

274. By way of example, and not limitation, in the absence of the defendants' conduct: (i) Asacol would have remained on the market; (ii) affordable generic version of Asacol would have become available beginning in or around July 2013; (iii) direct purchasers, such as plaintiff and other members of the classes, would have purchased less brand-name, supra-competitively-priced Asacol HD and Delzicol, and instead purchased affordable generic Asacol; and (iv) a generic version of Asacol HD would be available for sale.

275. The defendants' illegal acts and conspiracy to foreclose introduction into the U.S. marketplace of any generic form of the Asacol franchise drug delay the introduction into the U.S. marketplace of generic forms of the Asacol franchise drugs caused plaintiff and all members of the class to pay more than they would have paid for the Asacol franchise drugs, absent this illegal conduct.

276. Typically, generic versions of brand-name drugs are initially priced significantly below the branded counterpart. As a result, upon generic entry, direct purchasers substitute

generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand name drug continues to lose even more market share to the generics. This price competition enables all direct purchasers of the drugs to purchase generic versions of a drug at a substantially lower price, and/or purchase the brand name drug at a reduced price. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition.

277. Generic companies holding first-to-file exclusivity likewise have a keen financial interest in delaying their entry into the market in exchange for a share of the monopoly profits that their delay makes possible. And purchasers experience substantial cost inflation from these delays.

278. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, direct purchasers, such as plaintiff and members of the class, would have paid less for these drugs by (a) paying lower prices on their remaining brand purchases of these drugs, (b) substituting purchases of less-expense generic versions for their purchases of more-expensive brand versions, and/or (c) purchasing the generic versions of these drugs at lower prices sooner.

279. Thus, defendants' unlawful conduct deprived plaintiff and members of the classes of the benefits from competition that the antitrust laws are designed to ensure.

VIII. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

280. During the relevant time period, the defendants sold and will sell the Asacol franchise drugs across state lines.

281. During the relevant time period, plaintiff and members of the class purchased substantial amounts of the Asacol franchise drugs directly from Warner Chilcott/Allergan

defendants, and will purchase substantial amounts of Asacol HD from Zydus. As a result of defendants' illegal conduct, as described herein, plaintiff and the members of the two classes were compelled to pay, and did pay, artificially inflated prices for their ulcerative colitis treatments comprising mesalamine

282. During the relevant time period, the defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All defendants engaged in illegal activities, as charged in herein, within the flow of, and substantially affecting, interstate commerce.

IX. CLASS ACTION ALLEGATIONS

283. Plaintiff brings this action on behalf of itself and all others similarly situated under Federal Rule of Civil Procedure 23(a) and 23(b)(3).

> All persons or entities in the United States and its territories that purchased Asacol HD, and/or Delzicol, and/or generic Asacol HD in any form directly from Warner Chilcott, Allergan, or Zydus, including any predecessor or successor of Warner Chilcott or Allergan, at any time between July 31, 2013 until the anticompetitive effects of Warner Chilcott and Allergan's conduct cease (the "class").

284. Excluded from the class are Warner Chilcott, Allergan, Zydus, Cadila, and any officers, directors, management, employees, subsidiaries, and affiliates and all federal governmental entities.

285. Members of the direct purchaser class are so numerous that joinder is impracticable. Plaintiff believes that the classis numerous and widely dispersed throughout the United States. Further, the class is readily identifiable from information and records in defendants' possession.

286. Plaintiffs' claims are typical of the claims of the members of the class. Plaintiff and all members of the direct purchaser class were damaged by the same wrongful conduct of the

defendants, *i.e.*, they paid artificially inflated prices for the Asacol franchise drugs and/or these drugs' AB-rated generic equivalents as a result of defendants' wrongful conduct.

287. Plaintiff will fairly and adequately protect and represent the interests of the class. The interests of plaintiff are coincident with, and not antagonistic to, those of the class.

288. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

289. Questions of law and fact common to the members of the class predominate over questions that may affect only individual class members because defendants have acted on grounds generally applicable to the entire class, thereby making overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in defendants' wrongful conduct.

290. Questions of law and fact common to the Product Hop Class include:

a. Whether the Warner Chilcott/Allergan defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;

b. Whether the Warner Chilcott/Allergan defendants' anticompetitive scheme suppressed market entry of generic Asacol drug products;

c. Whether the Warner Chilcott/Allergan defendants' introduction of Delzicol and destruction of the prescription base of Asacol was predatory and anticompetitive;

d. Whether the Warner Chilcott/Allergan defendants withdrew Asacol out of legitimate safety concerns or for predatory and anticompetitive reasons;

e. Whether the Warner Chilcott/Allergan defendants surrounded an Asacol tablet with a capsule, then renamed it Delzicol, for procompetitive reasons or for the anticompetitive purpose of thwarting generic competition;

f. Whether there exist legitimate procompetitive reasons for some or all of the Warner Chilcott/Allergan defendants' conduct;

g. To the extent such justifications exist, whether there were less restrictive means of achieving them;

h. Whether direct proof of the Warner Chilcott/Allergan defendants' monopoly power is available and, if so, whether it is sufficient to prove defendants' monopoly power without the need to define the relevant market;

i. What is the extent of the relevant market or markets, to the extent a definition is required;

j. Whether the Warner Chilcott/Allergan defendants' scheme, in whole or in part, has substantially affected interstate commerce;

k. Whether the Warner Chilcott/Allergan defendants' scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of plaintiff and the members of the class;

l. Whether the Warner Chilcott/Allergan/Zydus defendants conspired to suppress generic competition for Asacol HD;

m. Whether, pursuant to the reverse payment agreement, Allergan's promise not to compete against Zydus's generic product constituted a payment;

n. Whether Allergan's payment to Zydus was for a purpose other than to induce delayed entry of generic Asacol HD;

o. Whether Allergan's compensation to Zydus was necessary to yield some cognizable, non-pretextual procompetitive benefit;

p. Whether Allergan's compensation to Zydus was large and unexplained;

q. Whether the reverse payment agreement created a bottleneck to further generic competition for Asacol HD;

r. Whether the Reverse Payment Defendants' challenged conduct harmed competition;

s. Whether Allergan possessed the ability to control prices and exclude competition for Asacol HD;

t. Whether the Warner Chilcott/Allergan/Zydus defendants' scheme, in whole or in part, has substantially affected interstate commerce;

u. Whether the Warner Chilcott/Allergan/Zydus defendants' scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of plaintiff and the class;

v. The quantum of overcharges paid by the class in the aggregate.

291. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

292. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

X. CLAIMS FOR RELIEF

COUNT ONE – MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2)
(Asserted against defendants Allergan and Warner Chilcott)

293. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

294. At all relevant times, the Warner Chilcott/Allergan defendants possessed monopoly power in the relevant market and possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

295. The Warner Chilcott/Allergan defendants engaged in an exclusionary conduct scheme that included at various times each of the following acts (among others):

a. Refusing to reformulate Asacol simply by removing DBP, as the FDA had requested, and instead adding a bogus capsule, the purpose of which was to render generic Asacol tablets non-substitutable;

b. Withdrawing Asacol tablets from the market rather than reformulating them to remove DBP;

c. Causing uncertainty as to whether the FDA would approve any ANDA for generic Asacol;

d. Cannibalizing the sales of Asacol;

e. Bribing doctors to switch prescriptions from Asacol to Asacol HD;

f. Switching prescriptions from Asacol to Asacol HD by promoting the latter for off-label uses;

g. Improperly listing the ’180 patent in the Orange Book;

h. Commencing and maintaining sham patent litigation against Teva;

i. Commencing and maintaining sham patent litigation against Mylan; and

j. Paying off Zydus to delay entering the market with generic Asacol HD.

296. The goal, purpose and/or effect of the Warner Chilcott/Allergan defendants’ scheme was to maintain and extend their monopoly power with respect to delayed-release mesalamine products – sold under the brand names Asacol, Asacol HD, and Delzicol. The Warner Chilcott/Allergan defendants’ illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic versions of the Asacol franchise drugs enabled the Warner Chilcott/Allergan defendants’ to continue charging supra-competitive prices for the products without a substantial loss of sales.

297. If manufacturers of generic Asacol franchise products had been able to enter the market and fairly compete in a full and timely fashion, plaintiff and members of the class would have substituted lower-priced generic products for some or all of their delayed-release mesalamine requirements, and/or would have received lower prices on some or all of their remaining branded purchases, at earlier periods of time and in far greater quantities.

298. As a result of the Warner Chilcott/Allergan defendants’ illegal scheme, plaintiff and the class paid more than they would have paid for delayed-release mesalamine products, absent the illegal conduct. But for the illegal conduct, competitors would have begun marketing

generic versions of the Asacol franchise drugs, resulting in cost savings to plaintiffs and direct purchasers.

299. During the relevant period, plaintiffs and the class purchased substantial amounts of Asacol, Asacol HD, and Delzicol directly from the Warner Chilcott/Allergan defendants. As a result of the Warner Chilcott/Allergan defendants' illegal conduct, plaintiffs and the members of the class were compelled to pay, and did pay, artificially inflated prices for their delayed-release mesalamine requirements. Plaintiff and all class members paid prices for Asacol, Asacol HD, and Delzicol that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic drugs instead of expensive brand-name Asacol, Asacol HD, and Delzicol; and/or (b) the price of branded Asacol, Asacol HD, and Delzicol was artificially inflated by the Warner Chilcott/Allergan defendants' illegal conduct.

300. The Warner Chilcott/Allergan defendants' scheme was, in the aggregate, an act of monopolization undertaken with the specific intent to monopolize the market for delayed-release mesalamine products in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT TWO – ATTEMPTED MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2)
(Asserted against defendants Allergan and Warner Chilcott)

301. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

302. At all relevant times, the Warner Chilcott/Allergan defendants' possessed substantial power (*i.e.*, monopoly power) or possessed a dangerous probability of achieving monopoly power.

303. With the specific intent to achieve a monopoly, the Warner Chilcott/Allergan defendants' attempted to acquire and/or willfully maintain monopoly power by means of restrictive or exclusionary conduct, rather than by means of greater business acumen, in order to exclude competition for the Asacol franchise drugs.

304. The goal, purpose, and effect of the Warner Chilcott/Allergan defendants' conduct was to delay and impair the sale of generic products in the United States at prices significantly below the Warner Chilcott/Allergan defendants' prices for Asacol, Asacol HD, and Delzicol, thereby effectively preventing the average market price for Asacol, Asacol HD, and Delzicol, and their generic equivalent products from declining dramatically.

305. By engaging in the foregoing conduct, Warner Chilcott/Allergan defendants have intentionally and wrongfully attempted to monopolize the relevant market in violation of the Sherman Act.

306. But for Warner Chilcott/Allergan defendants' unlawful conduct, generic manufacturers would have launched generic Asacol franchise drugs.

307. Plaintiff and members of the class have been injured in their business or property by reason of the Warner Chilcott/Allergan defendants' antitrust violations alleged herein. Their injuries consist of: (a) being denied the opportunity to purchase lower-priced generic Asacol franchise drugs; and (b) paying higher, supra-competitive prices for Asacol, Asacol HD, and Delzicol products than they would have paid in the absence of Warner Chilcott/Allergan defendants' conduct. These injuries are of the type the Sherman Act was designed to prevent, and flow from that which makes Warner Chilcott/Allergan defendants' conduct unlawful.

COUNT THREE – CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT (15 U.S.C. § 1) (Asserted All Defendants)

308. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

309. In or around December 2013, after two years of litigation related to the patents ostensibly covering Asacol HD, Allergan (then "Actavis") and generic competitor Zydus entered into an exclusion payment agreement under which Allergan agreed to pay Zydus substantial consideration in exchange for Zydus and Cadila's agreement to delay bringing a generic version of Asacol HD to the market.

310. The purpose and effect of the agreement

a. allocate to Allergan and Warner Chilcott 100% of the market for Asacol HD and its generic equivalents in the United States;

b. Prevent Zydus from selling a generic equivalent of Asacol HD in the United States until at least November 15, 2015 (or July 1, 2016);

c. Prevent Allergan from competing against Zydus with an authorized generic version of Asacol HD once Zydus launches its generic product; and

d. fix the price at which plaintiff and the class would pay for Asacol HD and its generic equivalents at supra-competitive levels.

311. The defendants are liable for the exclusion payment agreement under a rule of reason standard.

312. The agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

313. There is no legitimate, non-pretextual, procompetitive business justification for the payments that outweighs their harmful effects.

314. By engaging in the foregoing conduct, Exclusion Payment Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of 15 U.S.C. § 1.

315. As a direct and proximate result of the defendants' unlawful restraint of trade and unlawful maintenance of and conspiracy to maintain Allergan and Warner Chilcott's monopoly power, plaintiffs and members of the class paid artificially inflated prices for Asacol HD and its generic equivalents as described herein, and were harmed as a result.

316. But for the defendants' unlawful conduct, the Zydus, Cadila and other generic manufacturers would have launched generic Asacol HD earlier than they finally did: (a) "at-risk" (that is, while the patent litigation was still pending); or (b) after winning the patent suit; or (c) via a lawful settlement agreement without a large reverse payment from Allergan and Warner Chilcott.

317. Plaintiff and members of the class have been injured in their business or property by reason of the defendants' antitrust violations alleged herein. Their injuries consist of: (a) being denied the opportunity to purchase lower-priced generic Asacol HD products; and (b) paying higher, supra-competitive prices for Asacol HD products than they would have paid in the absence of the unlawful conduct, which continues to the present. These injuries are of the type the Sherman Act was designed to prevent, and flow from that which makes the defendants' conduct unlawful.

XI. DEMAND FOR JUDGMENT

WHEREFORE, plaintiff, on behalf of itself the class, respectfully pray the Court for a judgment that:

a. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the class, and declare the plaintiff as the representative of the class;

b. Enter joint and several judgments against defendants and in favor of plaintiff and the class;

c. Award the class damages (i.e., three times overcharges) in an amount to be determined at trial;

d. Award plaintiff and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

e. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XII. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiffs, on behalf of themselves and the proposed Class, demand a trial by jury on all issues so triable.

Dated: July 19, 2016

Respectfully submitted,

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